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MANUAL OF PATENT OFFICE PRACTICE

FOREWORD

Welcome to the *Manual of Patent Office Practice (MOPOP)*, a guide for patent examiners, applicants, agents and the public to the operational procedures and examination practices of the Canadian Patent Office.

Practices expressed in the MOPOP arise from the Office's interpretation of the *Patent Act*, *Patent Rules* and jurisprudence as of the date each chapter came into effect.

This manual is solely a guide and should not be considered to be a binding legal authority. In the event of any inconsistency between this guide and the applicable legislation, this legislation must be followed.

The manual will be updated periodically to reflect changes to the statutory, regulatory and jurisprudential framework governing patents in Canada. The revision date of a chapter is March 1998 unless otherwise indicated, and is listed on the Canadian Intellectual Property Office's web site at:

http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html.

Please note that the current version of the MOPOP does not cover all practices relating to the prosecution of applications filed prior to October 1, 1989.

Information regarding forthcoming updates to this manual, including periods of public consultation, may be found at:

http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00758.html.

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Chapter 1
Contacting the Patent Office

1.01 Location of the Patent Office

The Patent Office is located at Place du Portage I, 50 Victoria Street, Gatineau, Quebec. The general contact telephone numbers of the Patent Office are:

CIPO's Client Service Centre (General information):
Tel.: 1 866 997-1936 (TTY: 1 866 442-2476)
Fax: (819) 953-7620

CIPO's Mailroom:
Tel.: (819) 997-1727
Business hours: from 8:30 a.m. to 5:00 p.m. (EST), Monday to Friday

Finance:
Tel.: (819) 994-4682

1.02 Correspondence in person or by mail

All mail correspondence[1] for the Commissioner of Patents or for the Patent Office should be addressed to:

The Commissioner of Patents
Canadian Intellectual Property Office
Place du Portage I
50 Victoria Street, Room C-114
Gatineau QC K1A 0C9

All such correspondence addressed to the Commissioner may also be physically delivered to the Registered Mail Service of Canada Post, or any designated establishment as identified in the *Canadian Patent Office Record*[2] (CPOR). These designated establishments are:

1. Industry Canada
   C.D. Howe Building
   235 Queen Street, Room S-117
   Ottawa ON K1A 0H5
   Tel.: (613) 990-4582

2. Industry Canada
   5 Place Ville-Marie, Suite 700
   Montreal QC H3B 2G2
   Tel.: (514) 496-1797
   Toll-free: 1 888 237-3037

3. Industry Canada
151 Yonge Street, 4th Floor
Toronto ON M5C 2W7
Tel.: (416) 973-5000

4. Industry Canada
Canada Place
9700 Jasper Avenue, Suite 725
Edmonton AB T5J 4C3
Tel.: (780) 495-4782
Toll-free: 1 800 461-2646

5. Industry Canada
Library Square
300 West Georgia Street, Suite 2000
Vancouver BC V6B 6E1
Tel.: (604) 666-5000

Correspondence delivered during ordinary business hours to the Patent Office, anywhere other than at CIPO's mailroom (C-114), will only be considered to be received on the day it is delivered to CIPO's mailroom and date stamped.

1.03 Electronic correspondence

Correspondence sent electronically by facsimile or online in accordance with section 8.1 of the *Patent Act* constitutes the original; therefore, a duplicate paper copy should not be forwarded.

1.03.01 Facsimile transmissions

The Patent Office accepts facsimile transmissions in respect of applications or other correspondence. Facsimiles have to be addressed to the Commissioner using the following numbers[3] (facsimile equipment of CIPO's mailroom):

(819) 953-CIPO (953-2476) or
(819) 953-OPIC (953-6742)

The electronic transmittal report will constitute the acknowledgement that the correspondence has been received.

Facsimile correspondence which is sent to any facsimile number other than those indicated above, including those of a designated establishment, will be considered not to have been received.

When submitting a document by facsimile that also has a fee requirement, notification of the preferred mode of payment to be applied should be prominently displayed on the covering letter to ensure expedient processing.

1.03.02 Online correspondence via CIPO's website

Online correspondence addressed to the Commissioner for filing patent applications may be sent electronically via CIPO's website to the following addresses[4]:

https://strategis.ic.gc.ca/sc_mrksv/cipo/patbrev-filing/application/engdoc/pt_filing_form-e.html

or in French to:

https://strategis.ic.gc.ca/sc_mrksv/cipo/patbrev-filing/application/frndoc/pt_filing_form-f.html

Any other correspondence addressed to the Commissioner relating to applications and patents (e.g. fee payments, registering documents, requesting national entry of an international application), may be sent electronically via CIPO's website at the following addresses:

https://strategis.ic.gc.ca/sc_mrksv/cipo/patbrev-filing/application/engdoc/pt_correspondence-e.html

or in French to:

https://strategis.ic.gc.ca/sc_mrksv/cipo/patbrev-filing/application/frndoc/pt_correspondence-f.html

The document presentation requirements related to sections 69 and 70 of the *Patent Rules* apply to electronically submitted correspondence, including facsimiles. The acceptable file formats for documents submitted electronically via CIPO's website, such as assignments or specifications are: multi-page TIFF CCITT Group 4, black and white, at 300 DPI, or in PDF format. Sequence listings will have to be provided in both a multi-page TIFF or PDF file and in an ASCII file. Documents received electronically that do not meet these requirements will have to be replaced and submitted in an acceptable format.

1.04 Date of reception

In accordance with the above:

- Mail intended for the Patent Office and delivered, during business hours, to CIPO's offices in Gatineau will be accorded the date of reception by CIPO.
- Mail intended for the Patent Office and delivered, during business hours, to one of Industry Canada's regional offices listed in section 1.02, will be considered to be received on the date of reception in that office, only if it is also a day on which CIPO's offices in Gatineau are open. Mail delivered to a regional office on a day

when CIPO's offices in Gatineau are closed will be considered to be received on the next working day for CIPO. If, for example, mail intended for the Patent Office is delivered to Industry Canada's regional office in Toronto on June 24, it will not be considered to be received on June 24 as this is a day on which CIPO's offices in Gatineau are closed. Mail delivered to regional offices on June 24 will be considered to be received on the next working day for CIPO.

- Mail intended for the Patent Office and delivered through Canada Post's Registered Mail Service will be considered to be received on the date stamped on the envelope by Canada Post Corporation, if it is also a day on which CIPO's offices in Gatineau are open. If the date stamped on the Registered Mail is a day when CIPO's offices in Gatineau are closed, the mail will be considered to be received on the next working day for CIPO.

- Mail intended for the Patent Office and delivered, by electronic means of transmission, including facsimile, will be considered to be received by the Commissioner on the day that it is transmitted if received before midnight, local time at the Patent Office in Gatineau. When the Patent Office is closed for business, correspondence received on that day will be considered to be received on the next working day.

1.04.01 Filing of a document on statutory holidays (*Dies non*)

In accordance with section 26 of the *Interpretation Act*, any person choosing to deliver a document to a designated establishment, including the Patent Office in Gatineau, an Industry Canada regional office, or a Registered Mail establishment, where a federal, provincial or territorial holiday exists, is entitled to an extension of any time limit for the filing of the document that expires on the holiday, until the next day that is not a holiday. It is to be noted, in respect of provincial and territorial holidays, that the entitlement to the extension is dependent on the establishment to which the document is delivered and not on the place of residence of the person for whom the document is filed or of their agent. For this purpose, documents transmitted to the Patent Office by electronic means, including by facsimile, would be considered to be delivered in Gatineau, Quebec.

Operationally, the Patent Office has no practical way of keeping track of the establishment to which documents are delivered. Accordingly, where a person has a time limit for the filing of a document that expires on a provincial or territorial holiday but only delivers the document on the next day that is not a holiday, the Patent Office will assume that the document was delivered to an establishment that would justify an extension of the time limit. In such circumstances, it will be the responsibility of the person filing the document to ensure that they are properly entitled to any needed extension of the time limit. In doubt, the applicant can contact the Patent Office to get a confirmation of the filing date.

In addition to the extensions of time limits referred to above, in accordance with subsection 78(1) of the *Patent Act*, any patent time limit that expires on a day when the Patent Office is closed for business is deemed to be extended to the next day when the office is open for business. All persons are entitled to these extensions regardless of their place of residence or of the establishment to which documents are delivered.

The Patent Office takes the position that section 26 of the *Interpretation Act* applies to PCT international applications filed in Canada. Accordingly, where a person has a time limit under the PCT for the filing of a document in Canada that expires on a provincial or territorial holiday but only delivers the document on the next day that is not a holiday, the Patent Office will assume that the document was delivered to an establishment that would justify an extension of the time limit. The Patent Office, however, takes no position as to whether such extensions would be recognized by other countries and it will be the responsibility of the person filing the document to ensure that in other countries of interest they are properly entitled to any needed extension of the time limit by reason of rule 80.5 of the *Regulations under the PCT* or some other applicable law.

For the purposes of this chapter, the Patent Office has identified the following as being days that are not federal holidays but that are holidays in one or more provinces or territories:

- **Alberta**: 3rd Monday in February (Alberta Family Day)
- **British Columbia**: 1st Monday in August (British Columbia Day)
- **New Brunswick**: 1st Monday in August (New Brunswick Day)
- **Nova Scotia**: 1st Monday in August (Civic Holiday)
- **Ontario**: 1st Monday in August (Civic Holiday)
- **Quebec**: June 24 (St. John the Baptist Day)
- **Saskatchewan**: 1st Monday in August (Saskatchewan Day)
- **Yukon**: 3rd Monday in August (Discovery Day)

Section 20.04 of MOPOP lists the days that are closed for business for the purposes of subsection 78(1) of the *Patent Act*.

1.05 Interviews

Subject to the conditions imposed by subsection 6(3) of the *Patent Rules*, authorized correspondents, applicants and agents may meet with examiners about pending applications. Appointments must be arranged in advance so that the examiners will be available and prepared to discuss the prosecution of applications. Where an agent has been appointed, the agent must be present at the interview or have authorized it.

Interviews concerning the prosecution of applications, including applications that have received final action, may be requested at any stage of the prosecution and are conducted by the examiner in charge of the application. At these interviews, the examiners may provide further explanations about the objections they have made in a report or clarify certain points concerning the invention. However, interviews do not replace the normal prosecution of an application, and at these interviews, the examiners should never provide verbal opinions or agree to accept amendments to the specifications before receiving and assessing official correspondence from the applicants.

In the case of an interview with a new examiner in training, a senior examiner or a Patent Office section head must attend. Problems that do not concern the examination process are referred to the appropriate section of the Patent Office.

The Commissioner does not meet with agents or inventors about prosecution issues related to specific applications.

1.06 Client Feedback system

As part of its ongoing commitment to improve its services, the Patent Office encourages feedback from clients. Feedback is invited via CIPO's online Client Feedback system, which is located in the “Contact Us” section of CIPO’s website.

http://napoleon.ic.gc.ca/cipo/internet.nsf/comp-e

Using a simple online form, clients may submit a complaint, comment or compliment. Those wishing to receive a response are invited to include their name and other information. Feedback can also be submitted anonymously.

Where a reply is required, CIPO will provide an initial response within five business days. General matters are handled by CIPO's Client Service Centre. Questions or concerns of a more technical nature are routed to the appropriate subject-matter expert within the Patent Office.

CIPO's online Client Feedback system is intended to help CIPO’s clients to provide comments on its services and to resolve problems where applicable. Feedback is also used to help CIPO better understand how to improve its services.

It is important to note that the Client Feedback system is not intended for the prosecution of an application and cannot be used to respond to an official Patent Office requisition.

1.07 Publications related to Canadian documents

The CPOR is published weekly every Tuesday. It contains a list of all the patent applications open for public inspection and all the patents granted for the week ending with the Tuesday of the publication, and it also contains important notices. Copies of the CPOR are available via CIPO's website at the following addresses:

http://strategis.ic.gc.ca/patents/record

or in French at:

http://strategis.ic.gc.ca/brevets/gazette

Copies of Canadian patents and patent applications open for public inspection, as filed, can be downloaded in Adobe Acrobat format via CIPO's website at the following address:

http://patents1.ic.gc.ca/intro-e.html

or in French at:

http://patents1.ic.gc.ca/intro-f.html

These copies may also be purchased via the Reproduction and Sales Section of CIPO via CIPO's website using the "Order Form" link at the following addresses:

http://strategis.gc.ca/sc_mrksv/cipo/patents/pt_order_doc-e.html

or in French at:

http://strategis.gc.ca/sc_mrksv/cipo/patents/pt_order_doc-f.html

or by contacting:

Reproduction and Sales Section
Canadian Intellectual Property Office
Industry Canada
Place du Portage I
50 Victoria, Room C-229
Gatineau QC K1A 0C9

Tel.: 1 866 997-1936
Fax: (819) 953-9969

Endnotes for Chapter 1

1. For the purposes of subsections 5(2), 5(3), 54(1) and 54(2) of the *Patent Rules*

2. For the purposes of subsections 5(4), 5(5), 54(3) and 54(4) of the *Patent Rules*

3. In accordance with section 8.1 of the *Patent Act* and for the purpose of subsections 5(6), 5(7), 5(8), 54(5), 54(6) and 54(7) of the *Patent Rules*

4. In accordance with section 8.1 of the *Patent Act* and for the purpose of subsections 5(6), 5(7) and 5(8) of the *Patent Rules*

Chapter 2

Opening and inspection of documents

2.01 Inspection of documents

In accordance with Section 10 of the *Patent Act*, all applications that have been opened to public inspection, protests when associated with an opened application file and prior art filed pursuant to Section 34.1 of the *Patent Act* when associated with an opened application file, patents and re-examination files, and all documents associated with any of the above, shall be available for inspection on request in the Patent Office. This information will also be made available via Techsource at designated Industry Canada Offices across Canada.

A patent application open to public inspection will be called "opened" throughout this Manual. A patent application not opened to inspection by the public will be called "unopened" in this Manual.

2.01.01 Opening of applications

All patent applications, except those filed prior to October 1, 1989 and documents on file in connection therewith, shall be open to public inspection after the expiration of an eighteen-month confidentiality period (subsection 10(2) of the *Patent Act*). The confidentiality period is one of

i) eighteen months from the Canadian filing date, or

ii) where a request for priority has been made, eighteen months from the earliest filing date of any previously regularly filed application on which the request is based.

Applications filed under the Patent Cooperation Treaty (PCT) that include a designation for Canada and have not entered the national phase in Canada and documents on file in connection therewith will be available for inspection in the Patent Office as soon as possible after the expiration of eighteen months from the international filing date or the priority date thereof.

In accordance with subsection 10(2) of the *Patent Act*, an applicant may make a written request to have an application opened to public inspection before the expiry of the confidentiality period.

An application will not be laid open to public if it has been withdrawn at least two months prior to the expiration of the confidentiality period or a later date if the technical preparations to open the application to public inspection can be stopped (Sections 91, 92 and 145 of the *Patent Rules*).

A listing of applications opened to public inspection each week will appear in the Canadian Patent Office Record.

PCT applications entering the national phase in Canada after the date of publication by the International Bureau of the World Intellectual Property Organization in English or French will bear, as the laid-open date, the date of publication of the international application. This date will normally be within thirteen days after the expiry of eighteen months from the priority date or filing date of the international application.

2.01.02 Confidentiality of unopened applications

Unopened applications are confidential. Sections 10 and 11 of the *Patent Act* and sections 11, 91 and 92 of the *Patent Rules* apply. The Patent Office is required to protect the interest of the applicant by ensuring that only authorized persons are allowed to inspect unopened files. Individuals authorized to see the file by the applicant or the applicant's agent are permitted to do so. Individual persons, not known to the Patent Office, requesting access to a file must provide evidence that they have the right to see a file. A letter of introduction and authorization from the applicant or the applicant's agent, for example, would suffice. Inventors who have assigned all interest in their invention to others will not have access to the unopened file without authorization from the assignee or agent. If an agent has been appointed and the inventor has retained some interest in the application, the inventor may see the file and discuss the case with the examiner in general terms, but in accordance with subsection 6(3) of the *Patent Rules* an interview including a detailed discussion of the prosecution is permitted only in the agent's presence or with the agent's consent. An examiner will not discuss matters relating to the prosecution of an application with persons other than the agent or those who have the agent's permission to discuss the application.

2.01.03 Effect of withdrawal of priority on opening to public inspection

A request for priority may be withdrawn at any time before a patent is issued. If the applicant withdraws a request for priority before the expiry of the confidentiality period it may be possible to delay the opening of the application to public inspection (subsection 10(4) of the *Patent Act*). The withdrawal must be made within sixteen months of the filing date of the priority application, or a later date if the technical preparations to open the application to public inspection can be stopped (sections 91 and 145 of the *Patent Rules*). The application will then be laid open to public inspection at the end of the new confidentiality period (eighteen months from the Canadian filing or eighteen months from the earliest of any other priority date, if more than one priority was claimed).

2.01.04 Legal Implication of date of opening to public inspection

The opening to public inspection starts the protection period for a patentee in accordance with subsection 55(2) of the *Patent Act*, provided that the opened application is subsequently issued to patent.

2.02 Information on applications

Opened applications for patents may be accessed through use of the INQUIRE/Text database which provides the capability of searching for applications by cover page information, such as by number, the inventor's name or the international patent classification, or alternatively any such document may be located by conducting a word search of the text's subject matter.

2.02.01 Numbering of applications

Applications for patents filed after October 1,1989 are given unique numbers at filing. This number will be in the two million series of numbers and any patent issuing from such applications will bear the same number. A reissued patent and a reexamined patent will bear the same number as the original patent. Divisional applications are given a number in the two million series but different from the number of the original patent application.

Applications for patents filed prior to October 1, 1989 bear unique numbers. Patents issuing from these applications are given unique numbers in the one million series. Divisional applications arising from such applications will be given numbers that are different from those given the original patent applications. Applications for reissue will also be given unique numbers that are different from their original patent numbers.

2.02.02 Status information relating to applications identified by serial numbers

On payment of the fee set out in Schedule II, item 24, the Patent Office will indicate whether a Canadian application identified by serial number has issued to patent.

2.03 Searches by the public

It is a function of the Information Branch to help agents and members of the public in their searches by providing the necessary search tools and explaining their use. Searchers unfamiliar with Patent Office's classification systems and those searchers requiring further assistance are referred to the Classification Division where classification examiners will recommend a search pattern. In case of any doubt about a search pattern, the classification examiners may suggest that searchers consult examiners in a particular field. Examiners are expected to give such searchers specific directions where to search in their particular field of technology, but are not expected to carry out these searches themselves.

2.04 Opinions on opened applications

The Patent Office Staff will not express any opinion with respect to the claims of an opened application except on examination of the application, nor will they give any opinion concerning the final scope of those claims. Furthermore, they will not express a view as to whether any proposal presented would infringe the claims of an opened application.

2.04.01 Validity and interpretation of patents

Issued patents granted by the Patent Office are presumed valid under section 43 of the

Patent Act until such time as the Courts decide otherwise or the patent is made subject to reissue or re-examination procedures. Employees of the Patent Office may not comment on the validity of any issued patent, nor may they discuss how claims of any issued patent should be interpreted, or express a view as to whether they would be infringed by any proposal presented. Any member of the public requesting information of this type is advised to seek advice from a registered patent agent or a patent lawyer.

Chapter 3

Inquiries and information on pending applications

3.01 Inquiries by applicants

On occasion applicants, authorized correspondence or persons authorized by an applicant or authorized correspondent may wish to inquire about the status of their applications or ask when they will be acted upon. The procedure for handling such inquiries is outlined below.

3.01.01 Status inquiries

While applicants may inquire by letter about the status of their application, such inquiries should be kept to a minimum. The letter asking for status information should be restricted to the matter of status and not cover other subjects, since it will be stamped to indicate status only and returned to the applicant. If no examination has been requested on the application, the letter is stamped: "EXAMINATION NOT YET REQUESTED". If examination has been requested and the examination process has been started, the letter is either stamped: "UNDER EXAMINATION - NO OUTSTANDING ACTION - APPLICATION IN GOOD STANDING" or "UNDER EXAMINATION - THERE IS AN OUTSTANDING ACTION ON THIS APPLICATION - SEE ( ) MAILED ( )". The letter is initialled by the clerical staff.

When an inquiry is made by an inventor not represented by a patent agent, the Patent Office does not return the inquiry letter but writes to the inventor, explaining the status of the application.

When it is found that an application is not in good standing (i.e. it is abandoned), the applicant is advised of its present status by letter, and the reason for its abandonment. For example, the applicant will be told that it is abandoned for "failure to reply to the report of...". A letter would also be sent under other special circumstances, for example, if the application is before the courts.

Information about the status of unopened applications is given only to the authorized correspondent for the application, to the applicant or to a person authorized by the authorized correspondent or the applicant to receive the information.

3.01.02 Action inquiries

Applicants may ask by letter when the next examiner's action may be expected. Normally the applicant's letter will be returned after it has been stamped with the information: "THE EXAMINER EXPECTS TO REACH THIS APPLICATION IN ABOUT ( ) MONTHS". The blank space is filled in by the examiner. In those instances where examination has not yet been requested the applicant will be so informed.

3.02 Inquiries on pending applications (Section 11 of the *Patent Act*)

Under section 11 of the *Patent Act* information may be given to inquirers as to whether there is filed and pending in Canada an application, opened or unopened, that corresponds in subject matter and is related to a foreign patent by common inventors or applicants. No information is released about Canadian applications of different inventors/applicants directed to the same subject matter, nor is any search made to locate corresponding Canadian patents of the same inventors. However, information is supplied when there is at least one inventor or applicant common to both the foreign patent and a Canadian application.

Since the claims in a pending application may be changed at any time prior to issue, an affirmative reply is given to an inquiry under section 11 when there is a corresponding Canadian application disclosing but not necessarily claiming the invention in the foreign patent. The Patent Office looks to the description of the application, as it stands at the time of the inquiry. Matter which may have been deleted from the description is not considered.

Requests under section 11 must be made in writing and accompanied by the fee prescribed in Schedule II item 23 of the *Patent Rules*.

3.02.01 Searches based on foreign patents only

When an inquirer only makes reference to a foreign patent application or other specification that is not a patent, a search is not carried out under section 11 of the

Patent Act. Only foreign patents (including petty patents, utility models and inventors' certificates) may form the basis of an inquiry under section 11. "Design patents" are not included. Therefore, a requester should make certain that a document presented for section 11 search is in fact an issued patent.

3.02.02 How the search is conducted

Normally, an inquirer provides the Patent Office with the number of the foreign patent which includes the name of the inventor and/or the name of the applicant. A search is then made of all Canadian applications filed by the same inventor or by the same applicant.

Failure to indicate the name of the inventor reduces the likelihood of locating a corresponding application. The search covers all pending applications, including allowed applications and applications abandoned for less than 12 months. It also includes reissue applications. Applications filed abroad under the Patent Cooperation Treaty (PCT) and designating Canada will not be included in the search unless they have entered the national phase in Canada. A PCT application designating Canada can enter the national phase in Canada up to 42 months after its international filing date or its priority date, if any (subparagraph 58(3)(b)(ii) of the *Patent Rules*). In assessing pending Canadian applications, the examiner compares the invention claimed in the foreign patent with what could be claimed in the Canadian application. Thus, where the substance of the foreign patent is disclosed in the application as prior art, the pending application is not considered as being a corresponding application. Nor is a Canadian application considered to correspond to a foreign patent when the latter is a selection or improvement of the invention in the application.

Where the Canadian application discloses at least all of the invention of the patent and disclaims none of the subject matter, even tacitly, then the application is considered to correspond to the foreign patent and the inquirer is advised that an application for the same invention is pending in Canada. When the Canadian application discloses only part of the invention of the foreign patent (although other matter may also be described) the inquirer is advised that there is pending an application for part of the same invention but no further details may be supplied. Otherwise, the applicant is advised that a search of the records has failed to reveal a copending application in the name of the inventor (or applicant) that corresponds in subject matter to the identified foreign patent.

Chapter 4
Petitions and appointment of agents or representatives

4.01 The petition

While the abstract, description, claims and drawings of a patent application must be individually, or taken together, wholly in English or wholly in French (subsection 71(3) of the *Patent Rules*), the petition, assignment and other documents may be in either English or French but do not have to be all in the same language or in the same language as the specification (section 71 of the *Patent Rules*). The petition is a statutory requirement under section 27(2) of the *Patent Act* and must follow the format given in Schedule I, Form 3 of the *Patent Rules* (section 77 of the *Patent Rules*). The petition must commence on a new page (section 72 of the *Patent Rules*), must not contain drawings (section 74 of the *Patent Rules*) and must conform to the specific requirements of document presentation set forth in section 68 of the *Patent Rules.*

4.01.01 Amendment to the petition

The Patent Office will accept amended petitions subject to any other provision in the *Patent Act* and *Patent Rules.* No changes may be made to inventors or applicants unless to comply with sections 31, 49 or 50 of the *Patent Act.* The petition may be amended to correct clerical errors under section 35 of the *Patent Rules.* The Patent Office will not require the applicant to submit an amended petition to supply additional or corrected information. Such corrections or additions may be provided in a separate document. The original petition will be retained in the correspondence file of the application.

The requirement in subsection 27(2) of the *Patent Act* that an application contain a petition does not apply to PCT applications filed under the provisions of the Patent Cooperation Treaty (PCT). These applications are filed with a request in accordance with Article 4 of the PCT.

4.01.02 The title

In accordance with Form 3, an applicant must include in the petition or the request an appropriate title for the invention described in the application. Under paragraph 80(1)(a) of the *Patent Rules*, the title must be short and precise. The examiner will requisition an amendment of a title which does not conform to paragraph 80(1)(a) of the *Patent Rules*.

4.01.03 Public Servants Inventions Act

Under section 4 of the Public Servants Inventions Act, a public servant who makes an invention is required to advise the appropriate Minister of the invention and is required to disclose in any Canadian patent application that the applicant is a public servant. Public servants may not file an application for a patent outside Canada without written ministerial permission.

In the case of an invention by a public servant, the petition for patent must indicate that the inventor is a public servant.

4.02 Appointment of agents

Individual inventors may prosecute their own applications provided they have retained some interest in the invention. This does not extend to successors in title. However, an inventor may chose to be represented by a patent agent whose name appears on the register of patent agents which permits the agent to act on behalf of the inventor. Whenever all rights have been assigned and the assignment has been recorded in the Patent Office, an application must be prosecuted by a registered patent agent (see sections 20, 21, 22, 23 and 24 of the *Patent Rules*).

A patent agent may be appointed in the petition itself or separately by submitting to the Commissioner of Patents, a notice signed by the applicant (subsection 20(2) of the *Patent Rules*). The appointment must clearly identify the application to which it refers and the application serial number should be given, if known. When a change is made in the appointment of an agent, a notice signed by the applicant or agent must be submitted (subsection 20(3) of the *Patent Rules*, see also sections 23, 24 and 40 of the

Patent Rules).

4.02.01 Appointment of associate agents

An agent who does not reside in Canada cannot prosecute applications directly, but must appoint an associate agent who is a resident of Canada (subsection 21(1) of the *Patent Rules*). An agent who resides in Canada may also appoint an associate agent provided the associate agent has a Canadian residence (subsection 21(2) of the *Patent Rules*). Changes in the appointment of agents and associate agents may be effected by the applicant, the agent or associate agent (subsections 6(2), 20(3) and 21(4) of the *Patent Rules*.

4.03 Appointment of representative

An applicant who is the inventor and who does not appear to reside or carry on business at a specified address in Canada shall, on the filing date of the application appoint as a representative a person who resides or carries on business at a specified address in Canada (subsection 29(1) of the *Patent Act*). The appointee is deemed to be the representative of the applicant for all purposes of the *Patent Act* (subsection 29(2) of the *Patent Act*). However, correspondence from the Patent Office is not sent to the representative but directly to the inventor at the foreign address of the inventor. This includes examiner's reports, correspondence from the Commissioner and the patent grant. A representative may be appointed either in the petition (Schedule I, Form 3 of the *Patent Rules*) or by means of a separate document (section 78 of the *Patent Rules*). If applicant fails to appoint a representative, the application will be considered incomplete (paragraph 94(1)(i) of the *Patent Rules*).

A new representative may be appointed by the applicant or patentee at any time and must be appointed where requested by the Commissioner of Patents in accordance with section 29(3) of the *Patent Act*.

4.04 Status as small entity

Individual inventors, small businesses and universities may be entitled to reduced fees for filing applications for patents provided that the criteria defining a "small entity" in

Section 2 of the *Patent Rules* are met. Any applicant who desires to claim small entity status must so indicate in the request for obtaining a patent or in paragraph 7 of the formal petition, if one is filed.

4.05 Representative drawing

A single figure of the drawings is selected by the applicant or alternatively by an officer in the Patent Office to be representative of the drawings illustrating an invention. It is intended that an appropriately reduced version of this figure will be illustrated on the cover page of the opened patent application and the cover page of any patent which may issue from the application. The purpose of this drawing is to assist anyone searching the Canadian patent literature. The applicant is requested to identify what is considered to be the figure most representative of the invention in paragraph 7 of the formal petition.

4.06 Jurisprudence

The following decisions of the courts are of importance in considering the subject matter of this chapter:

petition

Beloit v Valmet	78 CPR (2d)	1	1984
Speery v John Deere	82 CPR (2d)	1	1984
Rothmans, Benson and Hedges	35 CPR (3d)	417	1991
Mobil Oil v Hercules	63 CPR (3d)	473	1995
	57 CPR (3d)	488	1994

assignment

Speery v John Deere	82 CPR (2d)	1	1984
Signalisation v Services	46 CPR (3d)	199	1992
Procter Gamble v Kimberly	40 CPR (3d)	1	1991
Positive Seal v M&I Heat	33 CPR (3d)	417	1991

Signalisation v Services	46 CPR (3d)	199	1992
Forget v Specialty	62 CPR (3d)	537	1995
	48 CPR (3d)	323	1993

license

Marchand v Peloquin	45 CPR (2d)	45	1978
Lubrizol v Imperial Oil	33 CPR (3d)	11	1990
	45 CPR (3d)	449	1992
Positive Seal v M&I Heat	33 CPR (3d)	417	1991
Signalisation v Services	46 CPR (3d)	199	1992
Forget v Specialty	48 CPR (3d)	323	1993
	62 CPR (3d)	537	1995

Chapter 5
Filing and completion requirements

5.00 Scope of chapter

This chapter applies to applications other than PCT national phase applications.

For applications filed under the provisions of the Patent Cooperation Treaty (PCT), see Chapter 22 of this Manual.

5.01 Filing of applications

An application for a patent shall be addressed to "The Commissioner of Patents" and shall be considered to be received by the Commissioner (i.e. filed) on the day that it is delivered to the Canadian Patent Office or to an establishment that is designated by the Commissioner in the *Canadian Patent Office Record* as an establishment to which correspondence addressed to the Commissioner may be delivered.

5.02 Requirements for a filing date

To obtain a filing date under subsection 28(1) of the *Patent Act* an application must conform to the requirements of Section 93 of the *Patent Rules*. It must include:

(a) an indication in English or French that the granting of a Canadian patent is sought;

(b) the name of the applicant;

(c) the address of the applicant or of a patent agent of the applicant;

(d) a document, in English or French, that on its face appears to describe an invention; and

(e) the application fee referred to in subsection 27(2) of the *Patent Act* and set out in Item 1 of Schedule II of the *Patent Rules*.

5.03 Completing the application

Subsection 27(2) of the *Patent Act* requires that an application be filed in accordance with the Regulations. Section 93 of the *Patent Rules* specifies the items required to be given a filing date. However, section 94 of the *Patent Rules* provides that even though an application has been given a filing date under section 93 of the *Patent Rules* it is incomplete unless it meets the requirements of sections 68, 69, 70 and subsection 94(1) of the *Patent Rules* at the time of filing.

Sections 68, 69 and 70 of the *Patent Rules* set forth the requirements for the presentation of documents and include items such as paper size, margins, line spacing and text character size.

Subsection 94(1) of the *Patent Rules* requires that certain information and documents, if not supplied at the time of filing, be supplied in order to complete the application. The information and documents required are as follows:

(a) a petition complying with section 77 of the *Patent Rules*;

(b) an abstract;

(c) a sequence listing, where required by paragraph 111(a) of the *Patent Rules*;

(d) a copy of a sequence listing in computer readable form, where required by paragraph 111(b) of the *Patent Rules*;

(e) a claim or claims;

(f) any drawing referred to in the description;

(g) an appointment of a patent agent, where required by section 20 of the *Patent Rules*;

(h) an appointment of an associate patent agent, where required by section 21 of the *Patent Rules*;

(i) an appointment of a representative, where required by section 29 of the *Patent Act*.

In all cases of incomplete applications, the office will make every effort to inform the applicant of the reasons for noncompliance by means of a courtesy letter. The letter will specify a time limit prior to which the application can be completed free. The time limit will be a date fifteen months from the filing date, or from the date of the earliest previously regularly filed application on which a request for priority is based, if any. The purpose of not requiring a fee for completing an application during the above period is to encourage applicants to provide the Patent Office with electronically scannable pages for TECHSOURCE and to ensure that all documents listed in (a) to (i) in the previous paragraph arrive at the Patent Office in a timely manner for laying open to public inspection under section 10 of the *Patent Act*.

If at the expiration of a time period of fifteen months from the filing date, or the priority date, if any, the application is still not complete, a Commissioner's Notice will be sent under subsection 94(1) of the *Patent Rules*. The Notice will requisition the applicant to complete the application within a period ending the later of three months after the date of the notice and twelve months after the filing date of the application. Completing the application after the notice has been received will require the payment of the completion fee specified in Item 2 of Schedule II of the *Patent Rules*. Failure to complete the application or to pay the fee within the time period specified in the notice will result in abandonment of the application.

5.03.01 Completing applications filed prior to October 1, 1996

Section 148 of the *Patent Rules* specifies that where an application other than a PCT national phase application did not, on the filing date of the application, contain the information and documents listed below, the application shall, for the purposes of section 73(2) of the *Patent Act*, be deemed to be abandoned if, after the expiry of the twelve-month period after the filing date, the applicant has not paid the fee set out in item 2 of Schedule II and filed the following information and documents:

(a) an abstract;

(b) an appointment of a patent agent, where required by section 20 of the *Patent Rules*;

(c) an appointment of an associated patent agent where required by section 21 of the *Patent Rules*; and

(d) an appointment of a representative, where required by section 29 of the *Patent Act*.

The reinstatement procedures set forth in subsection 16(4) of the Patent Cooperation Treaty Regulations as they read immediately before October 1, 1996 apply to an international application that was, before that date, deemed to be abandoned pursuant to subsection 16(3) of these Regulations.

5.04 Jurisprudence

The following decisions of the courts are of importance in considering the subject matter of this chapter:

filing date (extension of time)

Alexander v Canada	31 CPR (2d)	24	1976
Chinoin v Canada	31 CPR (2d)	32	1976
Didier-Werke v Canada	42 CPR (2d)	69	1978
Re: Procter & Gamble Co.	39 CPR (2d)	269	1979

Chapter 6
Ownership and registration

6.01 Introduction

Making an invention confers a property right on the inventor or in some cases on an employer of an inventor where the invention was made in the normal course of employment. This right includes the entitlement to apply for a patent and such right may be transferred to another person at any time with proper documentation (sections 49 and 50 of the *Patent Act*). As defined in section 2 of the *Patent Rules* a "transfer" means a change in ownership of a patent, of an application or of an interest in an invention and includes an assignment. Such a transfer may be effected at any time beginning at the date of invention and during the term of any patent which may issue in respect of that invention.

The history of transferring or passing on the right to a patent or an application is called the chain of title. The chain of title reflects any document that transfers ownership or that change the name of the owner. Such documents are, for example, assignments, mergers, change of name documents or wills.

By virtue of Section 50(1) of the *Patent Act*, the owner of a patent may assign the right, either wholly or partially, either generally or subject to territorial limitations, and either for the whole term of the patent or for any part thereof. A patent right may be regarded as divisible as to content, territory, or time, and in each case the assignee is to be regarded as the owner of the part assigned, and the assignor as the owner of the part not assigned. There may thus be more than one owner of the rights in a patent at one time.

6.02 Evidence

Where an application is filed in the Patent Office by a person who is not the inventor the applicant must, before a patent issues, file evidence that the applicant is a legal representative of the inventor and copies of documents effecting transfers relevant to the applicant's entitlement to file the application. The documentation and the fee for registration of the ownership should preferably be provided at the time of filing. In this case, the requirements of section 37 of the *Patent Rules* are complied with and the ownership documentation will be registered by the Patent Office and a certificate of registration will be sent to the applicant.

If the ownership documentation is not present or is incomplete the Patent Office will notify the applicant and will indicate the documents required for registration. This notification will be included in a courtesy letter which will inform the applicant of any deficiencies regarding the formal requirements of the application. The documentation required to establish ownership is not a completion requirement and is not subject to the same time limits as provided under section 94 of the *Patent Rules* for incomplete applications. However, as a matter of office practice, if the ownership documentation is not provided within 12 months of the Canadian filing date, or the national entry date of an application filed under the provisions of the PCT, the Commissioner will requisition the applicant to submit such documentation, requiring registration of the documents and the registration fee within 3 months of the requisition. If the applicant fails to reply in good faith to this requisition, the application becomes abandoned in accordance with section 97 of the *Patent Rules*. This 3 month time limit may be extended under section 26 of the *Patent Rules*.

In the case where an application is allowed, a patent shall not be granted to a transferee of said application unless the request for registration of the transfer is filed on or before the final fee is paid and the patent will issue in the name of the applicant as it existed at the time the final fee was paid. Transfers requested after the final fee is paid will not be processed until after the patent has issued (section 41 of the *Patent Rules*).

6.03 Registration

With the exception of transfers and exclusive license agreements, the Commissioner must register any document relating to a patent or an application upon the request of any person and upon payment of the fee set out in item 21 of Schedule II to the *Patent Rules* (section 42 of the *Patent Act*). Transfer documents relating to exclusive license agreements must be accompanied by proof of execution in accordance with subsection

49(3) and subsection 50(3) of the *Patent Act*. The following are examples of the type of proof that will be accepted for the purposes of section 49(3) and 50(3) of the *Patent Act*:

- an affidavit of a subscribing witness,
- the signature of a witness on the document, or
- the signature of the assignor if either the assignor or the agent of record indicates on the covering letter that the transfer or agreement was signed by the assignor,
- a corporate seal on the document.

In accordance with section 71 of *Patent Rules*, all documents submitted for registration must be in English or French or be accompanied by a translation into English or French.

Copies or photocopies of any document purporting to transfer ownership of a patent application will be registered by the Patent Office without requiring certification.

The following are required to proceed to register a transfer:

- the document must be signed and dated,
- a person signing on behalf of a company must specify his/her position and capacity to sign
- the complete address of the new owner must be given,
- all previous steps in the chain in title must have been recognized by the Commissioner of Patents;
- the document must identify the application or patent, either by the application or patent number, by priority information or any other suitable way that will allow the Patent Office to positively identify the correct document,

- the document must be specific with respect to which Canadian rights are being transferred and for amalgamations, mergers and consolidations it is not necessary to submit the entire document but only the relevant extracts and provide a precise statement of the portion of interest transferred.

In the case where there appears to be insufficient documentation, the Patent Office will send an office letter requisitioning clarification.

The following is a list of examples of various document types which can be registered:

(A) TRANSFER

Transfer per se
- assignment of all interest
- assignment of partial interest
- transfer of assets
- court orders
- wills
- amalgamations
- mergers
- consolidations

Updates
- change of names
- marriage certificates
- changes of incorporation
- affidavits

Other documents
- writ of Fieri Facias
- seizures
- court orders
- disclaimers

(B) AGREEMENTS
- notice of license agreement
- exclusive license agreement
- license agreements

- security agreements
- debentures
- compulsory licenses
- release of security agreements

6.04 Applicant for PCT applications at National Entry

Upon entry into the national phase in Canada an applicant who has filed an international application under the provisions of the Patent Cooperation Treaty (PCT) must comply with the requirements specified in subsection 58(1) of the *Patent Rules*.

The Patent Office requires certain documents concerning ownership for the granting of patents. The following situations may occur as outlined below.

1. The applicant who originally filed an international application requests entry into the national phase and provides the Patent Office with evidence by way of affidavit, statuary declaration or copies of documents effecting transfers or changes of names that the applicant is a legal representative of the inventor and copies of documents effecting transfers relevant to the applicant's entitlement to file the application (subsection 37(b) of the *Patent Rules*). No further documentation will be required by the Patent Office respecting ownership of the rights to the invention in this case, but the applicant will be requisitioned to register the necessary documentation in the Patent Office.

2. The applicant who originally filed the international application requests entry into the national phase but provides no documentation relating to ownership of the invention. In this case the Patent Office will advise the applicant by way of a courtesy letter that evidence meeting the requirements of section 37 of the *Patent Rules* as outlined above must be provided within 12 months of the date of national entry. If the ownership documentation is not provided within that time period, the Commissioner will requisition the applicant to submit such documentation, requiring registration of the documents and the registration fee within 3 months of the requisition. If the applicant fails to reply in good faith to this requisition the application becomes abandoned in accordance with section 97 of the *Patent Rules*. This three month time limit may be extended under

section 26 of the *Patent Rules.*

3. If the applicant entering the national phase is different from the applicant who filed the original international application, evidence that the applicant requesting national entry is the legal representative of the originally identified applicant must be provided (subsection 58(5) of the *Patent Rules*), if not already on file. Such evidence may be provided at the time of requesting national entry. If such evidence is not provided at that time, the Commissioner will requisition the necessary documents under section 25 of the *Patent Rules* which prescribes a three month time limit for compliance. The evidence required to satisfy subsection 58(5) of the *Patent Rules* must be provided to permit national entry. When this evidence is provided, the applicant will be accorded the national entry date on which the requirements of subsection 58(1) were satisfied. Although the form IB/306 is sufficient to satisfy the national entry requirement specified in subsection 58(5) of the *Patent Rules*, there will be a subsequent requirement to register the documents required by section 37 of the *Patent Rules*. The documents to be registered for that purpose must be such that the chain of title from the inventor to the present applicant is complete (sections 37, 38 and 39 of the *Patent Rules* and section 51 of the *Patent Act*).

4. In each of the situations outlined in 1, 2 or 3 above, the applicant will be notified by means of a courtesy letter of the action that must be taken to satisfy the Patent Office requirements concerning ownership.

6.05 Refusal of a joint inventor to proceed

When two or more persons jointly make an invention, all the inventors must join in applying for a patent and a patent is granted to them jointly. In case of disputes between joint applicants, Section 31 of the *Patent Act* applies, as follows:

(A) A joint inventor who refuses to file an application for patent;

By virtue of Section 31(1) of the *Patent Act*, If an invention is made by two or more inventors, and if one refuses to apply for a patent or if his whereabouts cannot be ascertained, the other inventor(s) may apply for a patent, and a patent may be granted in the names of those who apply, provided the Commissioner is satisfied that the joint inventor has refused to apply or cannot be found. Evidence to satisfy the Commissioner may be submitted by way of affidavit or statutory declaration.

(B) A joint applicant who refuses to further proceed with the application;

In accordance with section 31(2) of the *Patent Act* if an applicant who agrees in writing to assign his rights to another person and subsequently refuses to proceed with the application, or if disputes arise between joint applicants with respect to proceeding with an application, the Commissioner may allow that other person or joint applicant to proceed alone. To satisfy the Commissioner that one or more of the applicants ought to be allowed to proceed alone, evidence by way of affidavit or statutory declaration may be provided. All persons interested are entitled to be heard before the Commissioner.

6.06 Correction of transfer documents

The Patent Office will not require correction of minors errors in transfers or minor discrepancies between the transfer document and the petition. For example, company's abbreviations are not questioned such as Co. for Company, Inc. for Incorporated or LTD for Limited.

Any transfer of ownership which has been registered in the Patent Office may be corrected under the provisions of section 8 of the *Patent Act*.

6.07 Certificate of registration

Upon registration of a transfer including mergers, amalgamations and consolidations, a certificate of registration is produced and identified by number. The documents submitted for registration are scanned and annexed to the corresponding application file. The certificate and the documents submitted are returned to the sender.

No certificate is produced for a change of name.

The Federal Court has jurisdiction, on the application of the Commissioner or of any person interested, to order that any entry in the records of the Patent Office relating to the title to a patent be varied or expunged (section 52 of the *Patent Act*).

the title to a patent be varied or expunged (section 52 of the *Patent Act*).

6.08 Certified copies

Certified copies bearing the seal of the office may be obtained upon specific request and payment of the fee prescribed under item 26 of Schedule II of the *Patent Rules*. Certified copies of the certificate of registration or any document registered in Patent Office may be obtained in a similar manner.

6.09 Maintaining chain of title

In accordance with Rule 38 of *Patent Rules*, no transfer of a patent or application to a new owner is recognized by the Commissioner unless a copy of the document effecting the transfer from the currently recognized owner to the new owner has been registered in the Patent Office in respect of that patent or application.

6.10 Ownership rights

Once a transfer of ownership has been recorded, the application may not be withdrawn without the consent in writing of every currently recognized owner (subsection 49(2) of the *Patent Act*).

Revocation of the agent or representative and appointment of the new agent or representative has to be signed by the currently recognized owner or the patent agent currently of record (Section 20(3) of the *Patent Rules*).

6.11 Ownership information

The Patent Office maintains a register listing the names and addresses of all the owners of each application or patent. The ownership register may be consulted in the Public Search Room.

Chapter 7

Internal priority and convention priority

7.01 Filing requirements when priority Is requested

For applications filed after October 1, 1996:

The requirements for requesting priority in respect of a patent application are set out in section 28.4 of the *Patent Act* and sections 65, 88 and 89 of the *Patent Rules*. A request may be relied upon only if an application has been filed in Canada within 12 months of the earliest date on which any corresponding application has been filed in Canada or in any country belonging to the Paris Convention or in any World Trade Organization (WTO) member country (subparagraph 28.1(1)(a)(ii) and paragraph 28.1(1)(b) of the *Patent Act*).

Priority for applications filed under the provisions of the Patent Cooperation Treaty (PCT) is recorded in accordance with the procedures outlined in Section 7.01.02 below.

An application is not entitled to the "claim date" conferred by Section 28.1 of the *Patent Act*, unless the applicant requests priority based on a previously regularly filed application before the expiry of four months after the filing date of the application in Canada (paragraph 88(1)(b) of the *Patent Rules*).

The request for priority may be made in the petition or in a separate document (paragraph 88(1)(a) of the *Patent Rules*).

The applicant must provide the Commissioner with the date and country of each previously regularly filed application on which the request for priority is based, before the expiry of the four-month period after the filing date of the application in Canada (paragraph 88(1)(c) of the *Patent Rules*).

The applicant provide the Commissioner with the application number of each previously regularly filed application on which the request for priority is based, before the expiry of the later of the four-month period after the filing date of the subject application in

Canada, and the twelve-month period after the date of filing of the previously regularly filed application (paragraph 88(1)(d) of the *Patent Rules*).

No extension of time is permitted for requesting priority and providing the Commissioner with the date and country of each previously regularly filed application and for providing the application number of such applications (subsection 88(2) of the *Patent Rules*).

An applicant will be afforded the benefit of a request for priority only if the priority document adequately discloses at least part of the invention described in the subject application. Where a previously regularly filed application on the basis of which a request for priority is based is taken into account pursuant to sections 28.1 to 28.4 of the *Patent Act*, the applicant may be required to file a certified copy of such application and a certification from the patent office in which the application was filed, indicating the actual date of its filing (section 89 of the *Patent Rules*). If the previously regularly filed application is not written in either English or French, the applicant will be requisitioned to provide a translation in one of these languages (section 71 of the *Patent Rules*).

The benefit of a request for priority is not afforded by the Patent Office if an applicant has filed two applications in one or more countries for the same subject matter, and one of those filings was more than a year before the Canadian filing. Under normal circumstances no priority benefit may be based on the second application, even if it has been filed less than a year before the Canadian filing, except for new matter appearing in the second application. However, if the first filed application is considered never to have been filed in accordance with subsection 28.4(5) of the *Patent Act*, an inventor may be entitled to full priority rights based upon the subsequently filed application.

Priority is based on the specification in priority applications and thus not restricted to the invention claimed. A provisional patent application filed in a foreign jurisdiction such as a United States provisional application, may also serve as a basis for claiming priority for a Canadian application.

For applications filed prior to October 1, 1996 and after October 1, 1989:

A request for priority must be received by the Patent Office within six months of the filing date of the application (the subject application). The applicant must also provide the Commissioner with the date and country of filing and the application number of each previously regularly filed application on which the request for priority is based before the expiry of the six-month period after the filing date of the subject application (section 142 of the *Patent Rules*). Other than the time limits specified, all other provisions affecting priority are as given above.

No extension of time is permitted for requesting priority and providing the Commissioner with the date and country of each previously regularly filed application and for providing the application number of such applications (subsection 142(2) of the *Patent Rules*).

7.01.01 Internal priority

It is permitted to request priority based on a previously regularly filed Canadian application in a subsequently filed application provided the request is made within 4 months of the filing of the subsequently filed application. The applicant must provide the date of filing of the subject application within four months of the filing of the subsequently filed application and must also provide the application number of the subject application within the later of the four-month period after the filing date of the subsequently filed application and the twelve-month period after the date of filing of the subject application.

This practice provides an applicant the opportunity to file an application for patent as early as possible after an invention has been made in order to obtain the filing date for the disclosed subject matter. If the applicant subsequently makes improvements or alterations to the original invention, the applicant may file an additional application adding the new matter and requesting priority on the first filed application. This allows the applicant to maintain the original filing date for the subject matter disclosed in the first filed application while receiving a later filing date for the new matter. The applicant has the option of proceeding with both applications or abandoning the first application and proceeding with the second application.

7.01.02 PCT priority

The filing of an international application has the effect of filing a regular national application in each designated state. For the purposes of the Paris Convention, the effect of an international application is equivalent to that of a national filing. Priority rights, for example, may be based on an international application.

If the international application has acquired priority rights before the International Bureau based on an earlier filed national application, those rights would be extended to the applicant upon national entry in Canada.

For priority requests under the provisions of the Patent Cooperation Treaty (PCT) see Chapter 22 of this Manual.

7.02 Time limits for requesting priority under the Paris Convention

Applications requesting priority rights must be filed in Canada on or before the first anniversary date of the first filing in a Paris Convention country, a WTO member or Canada. The "twelve months" referred to in paragraph 28.1(1)(b) of the *Patent Act* ends on and includes the anniversary date of the first filing. However, if the anniversary date is a day when the Patent Office is closed for business, the filing may be made on the next day when the Patent Office is open for business (section 78 of the *Patent Act*).

7.03 Priority and OPI date in Canada

The date of the earliest previously filed application on which a request for priority is based will determine the date of opening to public inspection in Canada. In accordance with subsections 10(1) and (2) of the *Patent Act*, the application and all documents filed in connection with the application will be opened on the expiry of an 18 month confidentiality period beginning on the earliest priority date unless the applicant requests an earlier opening.

7.03.01 Withdrawal of priority

Under subsection 28.4(3) of the *Patent Act*, an applicant may withdraw a request for priority, either entirely or with respect to one or more previously regularly filed applications, by filing a request with the Commissioner. The Commissioner shall send a notice to the applicant advising that the request for priority has been withdrawn (subsection 90(1) of the *Patent Rules*). The effective date of the withdrawal of the request for priority will be the date the request for withdrawal is received by the Commissioner (subsection 90(2) of the *Patent Rules*).

7.04 Petty Patents and Authors' Certificates

The Patent Office recognizes convention priority based on petty patent applications, applications for authors' certificates, and utility models filed in foreign countries, since these are considered forms of patent applications. On the other hand, no priority may be based on a foreign application for an industrial design registration, design patents or their equivalent.

7.05 U.S. Continuation-in-part applications

Under some conditions, priority may be based on United States continuation-in-part applications. A continuation-in-part application may serve as a priority document for new matter disclosed in it and not in the original United States application if the Canadian application is filed within a year of the continuation-in-part.

Where a Canadian application is filed more than a year after the filing date of the original United States application, but less than a year after the continuation-in-part, the applicant is not entitled to priority on subject matter common to the two United States applications, even if the original has been abandoned. While under the Paris Convention an applicant may claim priority based on a second foreign application when the first has been abandoned, this is only so if there are no rights whatsoever remaining (Subsection 28.4(5) of the *Patent Act*). In the case of a continuation-in-part application, certain rights are carried over from the abandoned original application.

If both the original and the continuation-in-part applications are filed within the year preceding the filing of the Canadian application, priority may be based on both the original application and on the new matter in the continuation-in-part.

Where, therefore, priority is necessary to support a claim date in the prosecution of a Canadian application claiming priority from a United States continuation-in-part application only, it is necessary to identify the matter derived from the original United

States application, thereby to determine the priority rights of the applicant. Because a United States continuation-in-part application does not identify the new matter added to the original United States application, the applicant must submit certified copies of the original and continuation-in-part applications whenever required to do so by the Patent Office.

7.06 Multiple priorities

Subsection 28.4(4) of the *Patent Act* provides for multiple convention priorities.

A Canadian application, the subject application, may be a composite of several earlier filings of the inventor, and entitled to priority in respect of each for the subject matter contained therein, provided, that the subject application was filed within a year of the earliest filed application on which the request for priority is based.

Claim dates under section 28.1 of the *Patent Act* may be based on one or more previously regularly filed applications in the same or different countries which describe the subject matter of the claim in question. See also Chapter 15 of this Manual.

Chapter 8
Abstracts

8.01 Abstracts

Subsection 27(2) of the *Patent Act* provides the authority for the requirements of a patent application. An abstract is not a requirement for a filing date. An application, however, must contain an abstract in order to be complete (paragraph 94(1)(*b*) of the *Patent Rules*).

Section 79 of the *Patent Rules* sets forth the required form and content of the abstract as follows:

An application shall contain an abstract which shall

(a) contain a concise summary of the matter contained in the application and, where applicable, the chemical formula that, among all the formulae included in the application, best characterizes the invention;

(b) specify the technical field to which the invention relates;

(c) be drafted in a way that allows the clear understanding of the technical problem, the gist of the solution of that problem through the invention, and the principal use or uses of the invention;

(d) be so drafted that it can efficiently serve as a scanning tool for purposes of searching in the particular art; and

(e) shall not contain more than 150 words.

Section 72 of the *Patent Rules* specifies that the abstract should be provided on a page separate from the description. For clarity, it should have a separate heading, such as, "Abstract of the Specification". Since the abstract will be used as a search tool in the Patent Office's Techsource database, the text should avoid patent jargon so that it may be readily understood by technicians and scientists and other persons who are interested in obtaining information about opened patent applications and issued patents. It should provide a means for quickly determining the nature of the description so that the reader can decide whether a complete copy of the specification would be useful.

8.02 Reference characters in abstracts

Each main technical feature mentioned in the abstract and illustrated by a drawing in the application may be followed by a reference character referred to in a drawing, placed between parentheses (subsection 79(7) of the *Patent Rules*).

8.03 Examination of abstracts

Abstracts are subject to examination in respect to their conformance with section 79 of the *Patent Rules*.

8.04 Applications ready for allowance

When an application is allowable, except for the abstract, the examiner requisitions an amendment. The requisition notifies the applicant that the form of the abstract is the sole impediment to the prompt allowance of the application and that amendment to comply with section 79 of the *Patent Rules* is requisitioned within the prescribed time limit. Failure to respond will result in abandonment of the application.

8.05 Examples of abstracts

The following examples illustrate what are considered to be suitable abstracts.

(a) A heart valve with an annular valve body defining an orifice and having a plurality of struts forming a pair of cages on opposite sides of the orifice. A spherical closure member is captively held within the cages and moved by blood flow between open and closed positions in check valve fashion. A slight leak or backflow is provided in the closed position by making the orifice slightly larger than the closure member. Blood flow is maximized in the open position of the valve by providing a convex profile on the orifice-defining surfaces of the body. An annular rib is formed in a channel around the periphery of the valve body to anchor a suture ring used to secure the valve within the heart.

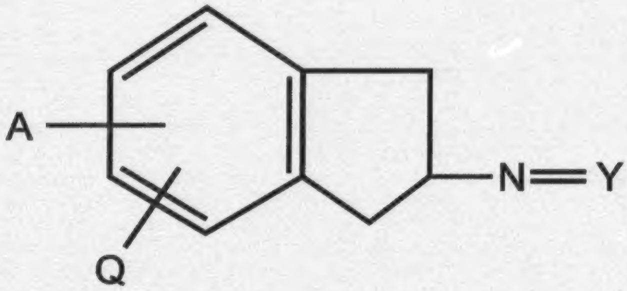
(b) A method comprising the use of heat to seal overlapping closure panels of a folding box made from paperboard having an extremely thin coating of moisture-proofing thermo-plastic material on opposite surfaces. Heated air is directed at the surfaces to be bonded, the temperature of the air at the point of impact on the surfaces being above the char point of the board. The boxes are moved so quickly through the air stream that the coating on the side of the panels not directly exposed to the hot air remains substantially non-tacky. A bond is formed almost immediately after heating. Under such conditions the heat applied to soften the thermo-plastic coating is dissipated after completion of the bond by absorption into the board itself, which acts as a heat sink, without the need for cooling devices.

(c) Amides are produced by reacting an ester of a carboxylic acid with an amine, using as catalyst an alkoxide of an alkali metal. The ester is first heated to at least 75°C. under a pressure of no more than 500 mm. of mercury to remove moisture and acid gases which prevent the reaction, and then converted to an amide without further heating.

(d) Process for the production of semiconductor devices, wherein a silicon oxide film is formed on a surface of a semiconductor substrate, followed by deposition of a layer of lead on the film. This combination is then heated at 500-700°C. for at least 10 minutes in an oxidizing atmosphere, whereby a passivating film forms, consisting essentially of silicon oxide and lead oxide. The temperatures employed are substantially lower than those conventionally used, and prevent deterioration of the device.

(e) Wool is heated at 50-65°C. for less than 15 minutes in an aqueous dispersion of 0.1-2 percent calcium hydroxide, washed, and then acidified to render it receptive to dyestuffs without adversely affecting the physical properties of the wool.

(f) Compounds of the formula:



wherein A and Q are hydrogen or alkoxy groups and Y means an alkylene group with 4 to 7 carbon atoms, are useful as plant desiccants.

(g) Method by which a token-passing local-area network having from 2 to 2^n modules is initialized, where n is an integer greater than zero. When connected into the network and energized, each module determines if the network is initialized and, if not, which module is to do so. Each module has a unique n bit network address. The module with the smallest network address energized before the network is initialized is identified and begins the process of initialization by transmitting tokens addressed sequentially to network addresses beginning with the next higher address than its own until a token so transmitted is accepted by an addresses module or until a token has been addressed to all network addresses other than that of the initiating module. After tokens are transmitted to all possible network addresses other than that of the initiating module, the initiating module generates a fault signal to indicate its status.

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Chapter 9
The Description

9.01 Scope of this chapter

The description, together with the claims, form the specification of an application.[1] Although the claims play a prominent role in the patent system, in that they define the scope of the exclusive privilege conferred by a patent, a proper description is fundamental to a valid patent. As was noted by the Supreme Court, "[d]isclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*".[2]

The present chapter discusses the various requirements for proper disclosure under section 27(3) of the *Patent Act* as well as the various requirements as to the form and content of a description under the *Patent Rules.*

9.02 General requirements of disclosure

The description must provide a clear and complete disclosure of the invention such that the person skilled in the art:

(1) can unambiguously identify what has been invented; and
(2) is enabled to practice this invention.[3]

In *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.*, Dickson J. noted that "the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired".[4] The description must be able to answer the questions "What is your invention?: How does it work?"[5] such that "when the period of the monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application".[6]

It is beyond doubt that the "public" referred to in the foregoing quote takes the form of the person skilled in the art.

9.02.01 Proper disclosure

The statutory requirements of proper disclosure are set out in subsection 27(3) of the *Patent Act*, which requires that:

> The specification of an invention must
>
> (*a*) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> (*b*) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
>
> (*c*) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
>
> (*d*) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

Thorson P. summarized the foregoing requirements in *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*,[7] noting that

> [t]he description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and must be as simple and distinct as the difficulty of description permits. It must not contain erroneous or misleading statements calculated to deceive or mislead the persons to whom the specification is addressed and render it difficult for them without trial and experiment to comprehend in what manner the invention is to be performed. It must not, for example, direct the use of alternative methods of putting it into effect if only one is practicable, even if persons skilled in the art would be likely to choose the practicable method. The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed. The description must also give all information that is necessary for successful operation or use of the invention, without leaving such result to the chance of successful experiment, and if warnings are required in order to avert failure such warnings must be given. Moreover, the inventor must act *uberrima fide* and give all information known to him that will enable the invention to be carried out to its best effect as contemplated by him.[8]

The foregoing touches on both aspects of a sufficient disclosure: that it set out in clear and precise terms what the invention is (i.e. a correct and full description), and that it provide sufficient instructions to the person skilled in the art so that this person is enabled to reproduce and successfully operate the claimed invention.

9.02.02 Addressee is the person skilled in the art

The specification of an invention is directed to a person skilled in the art or science to which it pertains, or with which it is most closely connected.[9] Whether or not a description is sufficient depends on the interpretation it would be given by the person skilled in the art, who must interpret it with a mind willing to understand[10] and desirous of success.[11]

The person skilled in the art is competent, and represents an average, logical but unimaginative worker in the field.[12] This person is neither a dull-witted incompetent nor a creative, intuitive expert,[13] albeit that in a highly technical field the person skilled in the art may be presumed to have expert-level knowledge and skills.[14] Furthermore, the person skilled in the art is reasonably diligent in keeping up with advances in the field or fields of relevance to the invention,[15] and has the advantage of being multilingual and thereby being able to comprehend prior art in any language.[16]

In addition, the person skilled in the art need not be an actual individual; they are a fictitious construct and can represent a team of individuals whose conjoint knowledge is relevant to the invention in suit.[17]

In order to properly assess whether a correct and full description of the invention has been provided, it is necessary to identify the person skilled in the art to which the application is directed.

In accordance with paragraph 80(1)(*b*) and 80(1)(*d*) of the *Patent Rules*, the description must indicate the technical field of the invention and must allow an understanding of the technical problem being addressed and the solution to that problem through the invention.[18] The person skilled in the art will be competent in the field or fields of relevance to the invention.

A complexity arising from the nature of the person skilled in the art is that, as a general rule, neither the inventors nor the examiner may be directly equated to this person. Examiners and inventors, for example, are not free of creativity and intuition. They may have knowledge that surpasses that expected of the person skilled in the art in a given field, but again may not be as skilled in other fields of the invention as this person. During examination, an examiner must attempt to interpret the application and the prior art using the appropriate knowledge that the person skilled in the art would have possessed at the relevant date [see 9.02.03]. This may be particularly challenging where knowledge in the field at the date of examination has significantly developed since the relevant date, and particularly where certain views held at the relevant date have subsequently been found to be incorrect.[19]

Where the precise nature of the person skilled in the art is relevant for resolving an issue during examination, the examiner will determine who this person is and will take due account of any representations made by the applicant on point.

9.02.03 Description supplemented by common knowledge

A description sufficient to allow the person skilled in the art to practice the invention with the same success as the inventor is said to be enabling. Since the person skilled in the art is the addressee of the description, it is not necessary for common knowledge to be comprehensively disclosed nor to teach to the person skilled in the art things that would be plainly obvious to them.[20]

The date at which the person skilled in the art brings their knowledge to bear on the application is the date on which the application came into their possession; that is to say, the publication date.[21]

Since the common general knowledge may develop between the filing date and the publication date, this theoretically means that a specification that was not enabling as filed could nevertheless, on the basis of more extensive common general knowledge, be enabling by the publication date. However, the invention must still be fully described as of the filing date, and the utility of the invention must have been established no later than at this date [see 9.04].

9.02.04 Misleading or erroneous statements

The person skilled in the art will read a description with a mind willing to understand and desirous of success. They will use their common general knowledge to supplement the description in order to successfully operate the invention, and will overlook obvious errors or omissions that can be readily corrected.[22]

Where, however, a description includes statements that direct the person skilled in the art to attempt to practice the invention in a manner contrary to their common general knowledge, the person skilled in the art will nevertheless follow these explicit instructions. Where the manner of operation so disclosed will in fact not work to achieve the promise of the invention, the description does not comply with subsection 27(3) of the *Patent Act*.[23]

[For guidance regarding misleading definitions in the description, see 9.05.03.]

9.02.05 Addressee not to be presented with problems to solve

The person skilled in the art can be called upon to perform routine experiments to ensure proper operation of an invention, but must be able to practice the full scope of the invention without undue burden or the need to exercise their inventive ingenuity.

If the person skilled in the art is called on to solve problems in such a manner that undue burden or an inventive step are required, the description is insufficient (and the attendant claims are unsupported).[24] The obligation of the patentee for proper disclosure in this sense was described in *Rice v. Christiani & Nielsen* as:

> [h]e must so draft his specification, that a person having a competent knowledge of the industry concerned [...] will be able readily to ascertain from it the relation the invention bears to the existing knowledge in the industry, and so that one should not be called upon to do experimental work in order to discover how the invention may be made operative. There must be an open exposition by the patentee of everything that is necessary for the easy and certain procurement of the commodity for which the patent was granted. The patentee is not to tell a man to make an experiment but to tell him how to do the thing.[25]

H.G. Fox later described the relationship between the specification and the person skilled in the art as follows:

> [t]he person to whom the specification is addressed is presumed to possess all the existing knowledge common to the art to which the invention relates; this knowledge he must bring to bear in interpreting the specification. But he is not required to exercise or to be possessed of more, and, if the specification contains something that necessitates the working out of a problem, the patent cannot be supported.
>
> Where a specification describes an invention sufficiently clearly to enable a reasonably skilled workman to make use of it, even though some experiments are necessary, the patent will be good so long as those experiments do not require any exercise of the inventive faculty.[26]

In certain arts, it is common to describe an invention as relying on materials having certain required properties (a metal with a certain ductility; an insulator with a certain dielectric value, a molecule with a certain dipole moment), rather than by naming the materials explicitly. This is permissible as long as identifying those materials that have the required property does not require undue burden or inventive effort.

Requiring the absence of inventive effort implies that the solution to the problem being addressed must be readily apparent to the person skilled in the art (i.e. obvious). Solving a problem with a readily apparent solution is routine, and a description that requires the solving of such a problem could nevertheless be considered to be sufficient. The Courts have noted that it can be considered uninventive to engage in "routine testing to determine characteristics of known compounds, not undertaken for the purpose of 'searching for something novel', but rather for the purpose of verifying the actual attributes of already known compounds".[27]

While verifying the predicted or predictable properties of known compounds may therefore be considered to be routine,[28] "verification" means "confirmation" and determining the unexpected and unpredictable properties of new compounds is consequently not "verification".[29]

This reasoning can be extended to disciplines other than the chemical arts by formulating the statement as: a certain amount of routine testing is permitted in order to identify suitable materials for operating an invention, presuming the person skilled in the art knows or has been taught the necessary properties, how to determine them, and broadly what existing materials are likely to possess them.

Examples:

1. An invention describes a particular type of flange for connecting a plumbing fixture to a pipe, wherein it is necessary to construct the flange using a metal whose ductility is within a certain range. Identifying this operative ductility range is the discovery underlying the invention. Several metals having the necessary ductility are identified, and general teachings are given as to what types of metals are likely to have the necessary property. Testing ductility is within the common general knowledge of the person skilled in the art, and is routine.

Claim:

> 1. A flexible flange for connecting a plumbing fixture to a pipe, said flange comprising a metal having ductility in the range x-y and [...]

Analysis: The claim is given breadth by defining the flange in terms of a metal having ductility in the defined range, rather than in terms of specific operative metals. Whether or not the claim as defined is enabled depends on whether it can be operated without placing undue burden on the person skilled in the art. This depends on whether the person skilled in the art can readily identify suitable metals. Given that the person skilled in the art can test a given metal to determine whether or not it has the necessary ductility, that for many metals this data is already available in published references, and that the description suggests which metals are likely to be suitable, there is no invention in identifying metals that have the necessary property. Verifying the properties of known metals is "routine", and the person skilled in the art has not improperly been presented with problems to solve.

2. An applicant asserts as their invention drug compositions having very uniform release profiles for the active ingredient. Certain embodiments are disclosed based on particular salts of protected cyclic amines, but the invention is claimed in terms of drug compositions having the beneficial release profile, and not in terms of drug compositions of the particular family of salts.

Claim:

1. A medicament having a release profile characterised by [description of the profile]

Analysis: Consider that the release profile achieved is an unexpected and very beneficial property of the specific salts disclosed. The description does not disclose what chemical properties of the salt led to the defined release profile, nor does it guide the person skilled in the art as to what other compounds may provide a similar result. In order to operate the full scope of the claim, the person skilled in the art would have to solve the problem of identifying all the other salts that would lead to the same release profile. Since the identity of these other salts (presuming some may exist) is unobvious, an inventive step is associated with their identification. The description is insufficient to support the invention as broadly asserted.

9.02.06 Theory of the invention

As a general proposition, it is not necessary for the description to provide a theory as to why the invention operates as it does. The requirement is, simply, that the description teaches the person skilled in the art what the invention is and how to make it operate to provide the promised benefits.

Thus, as noted in *Apotex v. Wellcome*, "[i]t is generally not necessary for an inventor to provide a theory of why the invention works. Practical readers merely want to know that it does work and how to work it".[30]

This general proposition, however, has to be understood in an appropriate context. The Supreme Court thus added to the comment quoted above by stating, in respect of an invention relying on sound prediction, that "[i]n this sort of case, however, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly".[31] It can consequently be understood that if the utility of the invention is predicated on a sound prediction [see 12.08.04], and the line of reasoning depends on an understanding of the theory as to why the invention works, it may not be possible to properly express the line of reasoning unless this theory is disclosed.

9.03 Disclosing a solution to a practical problem

As was noted by the Supreme Court in *Apotex v. Wellcome*, the granting of patents is "a method by which inventive solutions to practical problems are coaxed into the public domain".[32] Being a solution to a practical problem is what provides to the invention the practical utility necessary for patentability.

The description must put the person skilled in the art in a position to appreciate the nature of the problem being solved and the solution provided by the invention. For applications filed on or after October 1, 1996, paragraph 80(1)(*d*) of the *Patent Rules* explicitly provides that the description shall

> *describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution.*

In order to solve a practical problem, the solution must be in a form that can interact directly with the physical world and, hence, that will itself enable a person skilled in the art to obtain the intended result or benefit. That is, a patent is given for "the means by which a result is obtained ... rather than the result itself".[33] These means must consist of one or several elements, where an element in this sense could be either a physical object (a machine, article of manufacture or composition of matter) or a step leading to a physical effect in an art or process.

The group of elements that are made use of to obtain the benefit of the invention may, in combination, be referred to as the "practical form" of the invention (i.e. the form in which the invention may be practised). The practical form includes all the elements required to provide the utility of the invention.

In order for the description to properly disclose the practical form, it must supplement the common general knowledge of the person skilled in the art so as to put the invention into the hands of this person. Any novel element must therefore be fully described, as it was necessarily not previously known. Also, those elements (new or old) the person skilled in the art would not have known to use in combination to achieve the objects of the invention must be described, not only individually but in the appropriate combination.

For the description to disclose a patentable invention, it must describe (and the claims define) all the elements necessary to provide the useful result in a novel and inventive manner, and without which elements the solution would cease to be inventive.[34]

It is also necessary that the description provide such instructions as are necessary for the person skilled in the art to understand, where applicable, the interrelationship of the elements necessary to provide the practical form of the invention. The invention must be described so that, colloquially speaking, "the wheels will go round",[35] and must not require that the person skilled in the art perform modifications to the invention described in order to make it work.[36]

Although external documents may be referred to in the description, the invention must be described and enabled by the description alone as interpreted by the person skilled in the art in view of their common general knowledge. Specific prior art knowledge (e.g. information only available in one or a few documents, and which has not been shown to be commonly known and accepted) may be considered not to be "common general knowledge", and in such cases those specific teachings from the prior art necessary to describe or enable the invention must be included in the description in order to provide a full and complete disclosure.

It is not necessary to supplement a description of the foregoing with a description of those elements that would be self-evidently necessary to operate the invention, and whose use in the context of the invention as described would be obvious to the person skilled in the art.[37]

9.04 Establishing utility

As noted in 12.08.03 of this manual, an applicant must be in a position to establish the utility of their invention, by demonstration or sound prediction, no later than at the filing date of their application.[38]

As a general proposition, where the utility of an invention is to be established by demonstration, the factual basis that constitutes the demonstration must have existed at the filing date but need not have been included in the description.[39]

Where it is not evident from the description that the utility of an invention was established by demonstration, an examiner must presume that the applicant is relying on a sound prediction for this purpose. In such cases, an examiner may object to a lack of established utility if no factual basis was disclosed upon which it could be concluded that utility had been properly established. If the utility of the invention had been established by demonstration, the applicant can establish this by submitting the relevant factual basis by way of affidavit.

The utility of an invention, particularly where the essence of the invention is to provide something having new or improved utility, may be interrelated with the inventive step of the invention.

During prosecution, amendment to the claims may appear to alter the nature of the invention. Care must be taken to ensure that the inventor was, no later than the filing date, in possession of the invention asserted in the amended claims. Inventive ingenuity can not post-date filing.[40] This is particularly relevant where features not identified in the original specification as being related to specific advantages are subsequently asserted as rendering the claims non-obvious over prior art disclosures. It is important to consider whether the description teaches that the elements in question are simply optional, or are essential elements of preferred embodiments. Where the inclusion of an element will lead to additional benefits over the invention as broadly disclosed, it should be viewed as an essential element of the "narrower invention" (the subject-matter in a claim of narrower scope).

9.04.01 Sound prediction

The doctrine of sound prediction was given specific form by the Supreme Court, which noted that a sound prediction consists of three elements [see section 12.08.04 of this manual]:[41]

(i) a factual basis for the prediction;
(ii) an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and
(iii) proper disclosure.

The aspect of "proper disclosure" means that the description, when read in view of the relevant common general knowledge, must be sufficient to enable the person skilled in the art to soundly predict that the invention would work once reduced to practice.[42]

9.04.01*a* Disclosure of the factual basis

The factual basis needed to render the line of reasoning sound must be disclosed. If some or all of the facts being relied on are found in another publicly available document, this document must be properly identified.[43] Any necessary facts that are not otherwise publicly available must be included in the description.[44]

A factual basis does not by necessity mean experimental data.[45] Established principles and laws are also factual, and to the extent that these form part of the sound line of reasoning the foregoing considerations for proper disclosure apply.

The term "factual basis" implies support and proof. Simple, unsubstantiated statements in the description suggesting that the invention will work are not considered to be factual.[46] Similarly, while an applicant can include "prophetic examples" in their application, they have little value in providing support. A prophetic example is necessarily a statement of what might be, rather than what is, and is therefore not "factual".

As noted in section 12.08.04*a* of this manual, evaluating what will be a sufficient factual basis for a sound prediction must be conducted on a case-by-case basis, and will depend on such factors as:

(i) the scope of the claims;
(ii) the state of the art;
(iii) the nature of the invention and its predictability; and
(iv) the extent to which the applicant has explored the area claimed, for example by conducting experiments which provide factual support for the utility asserted.

A broad claim, for example, may well require a greater factual basis than a narrow claim. A claim in an established field might benefit from a more developed common general knowledge than one in an emerging field. The necessity to disclose or explicitly refer to the necessary support will depend both on the amount of support required and on how much of that support is already known to the person skilled in the art.

9.04.01*b* Disclosure of the sound line of reasoning

The person skilled in the art must also appreciate the sound line of reasoning that connects the factual basis to the conclusion that the invention has the promised utility.[47]

Here again, the description must provide whatever explanation is necessary to supplement the common general knowledge of the person skilled in the art so as to permit them, in view of the factual basis provided, to soundly predict that the invention will have the utility proposed.

The sound line of reasoning will usually involve an understanding at some level of the theory of the invention [see 9.02.06], and may depend e.g. on structure-activity relationships or accepted scientific principles or laws. The extent to which the sound line of reasoning must be described can only be evaluated on a case-by-case basis, and will depend on similar factors to those related to the factual basis.

As a disclosure requirement, the sound line of reasoning cannot be provided post-filing. Explanations during prosecution as to the nature of the sound line of reasoning can only be considered to the extent they explain why the person skilled in the art would have appreciated the sound line of reasoning on the basis of the description as filed and their common general knowledge.

Since the disclosure is directed to the person skilled in the art, the disclosure must allow that person to make a sound prediction. It is not enough that the description disclose information that allows for a sound prediction only when interpreted in view of proprietary knowledge possessed by the inventors alone or expert level knowledge beyond that expected of the person skilled in the art.

9.04.02 Selections

Selections are inventions based on the identification, from a prior teaching, of certain previously unrecognized advantages possessed by some sub-set of the prior teaching.

The accepted requirements of a selection are that:[48]

(i) the selection be based on some substantial advantage;
(ii) the whole of the selection must possess the advantage; and
(iii) the advantage must be in respect of a quality of a special character peculiar to the whole selection.

It is important to note that the advantage (which can include avoiding a substantial disadvantage) must be in comparison to the overall group from which the selection has been made, and be made on the basis of sufficient representative testing and not simply a comparison to a few isolated members of that group.[49]

The newly discovered and unexpected advantage is what provides to the selection the utility and inventive step upon which its patentability rests.[50] Its novelty rests on the fact that the selected aspects of the prior teaching had not previously been made: per Maughan J. in *I.G. Farbenindustrie*, "[i]t must be remembered, of course, that the selected compounds have not been made before, or the patent would fail for want of novelty".[51]

Although there is no special or higher disclosure burden for a selection by comparison with any other type of invention, the advantage (and, if unclear, the new utility arising from the advantage) must be properly disclosed for there to be an invention.[52] If there is no way to assess the purported "advantage", there is no way for the person skilled in the art to appreciate that an invention has been "correctly and fully" described. Again from *I.G. Farbenindustrie*, an inventor "has in truth disclosed no invention whatever if he merely says that the selected group possesses advantages. Apart altogether from the question of what is called sufficiency, he must disclose an invention; he fails to do this in the case of a selection for special characteristics, if he does not adequately define them".[53]

A purported selection whose utility has not been established, by demonstration or sound prediction, is necessarily not an invention. Establishing that there is, in fact, an advantage requires that some point of reference be disclosed. Mere statements that a certain embodiment of an identified group is "preferred" or possesses an otherwise unspecified advantage or benefit or improved property are not sufficient to adequately disclose the substantial advantage necessary to establish inventive selection.[54]

9.04.03 Combinations

A combination, in the sense the term is used herein, is an assemblage of parts (often of known parts) whose conjoint use leads to a result that is "different from the sum of the results of the elements" that make it up and "that is not attributable to any of the elements but flows from the combination itself and would not be possible without it".[55] Such a result may conveniently be termed a "unitary" result.[56]

A patentable combination has been explained in the following way:

> it is accepted as sound law that a mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, but that where the old integers when placed together have some working inter-relation producing a new or improved result then there is patentable subject matter in the idea of the working inter-relation brought about by the collocation of the integers.[57]

Where several parts are used together, each providing its expected result and the whole not leading to a unitary result, the assemblage is referred to as a "mere aggregation",[58] or simply as an "aggregation", to distinguish it from a true combination.

The utility of a combination is the unitary result it provides, and it is this result that must be established by demonstration or sound prediction.

Where, having described the structure of the combination, it would not be clear to the person skilled in the art what unitary result it achieves, a correct and full description of the result itself may be necessary to show that the combination is useful and inventive and to distinguish it from a mere aggregation.

9.04.04 Chemical combinations and synergy

In the chemical arts, different compounds or products are often combined in order to realize new results. The concept of combinations applies equally to chemical inventions as to any other.

A chemical combination refers to a physical, as opposed to chemical, combination of compounds or products. Generally, implementing the physical acts of mixing or physically combining different compounds or products does not require inventive activity. The inventive step in a chemical combination, by consequence, is typically closely associated with the utility of the combination, and generally arises from a recognition that the combination (as opposed to its individual components) unexpectedly provides a specific unitary result.

Where the combination leads to a new unitary result or one that is different from what the person skilled in the art would have expected the combination to be suitable for, the utility of the combination to produce that result must necessarily be established.

In some combinations, compounds having known activity are combined and jointly applied to achieve an enhanced result. That is, the activity or effect of the combination as a whole is greater or otherwise better than the result that would have been expected from the joint use of its individual components. In order to establish that such a result has been produced, it is necessary for the person skilled in the art to be aware of the point of reference (the result to be expected from combining the individual components), either by virtue of their common general knowledge or in view of the description. The need for a point of reference in such cases is analogous to the need for a point of reference when making an inventive selection [see 9.04.02].

Where the compounds have been jointly applied to their known purpose, the enhanced result may, as a matter of convenience, be referred to as a synergistic effect.

Where a first compound has been applied to its known purpose and another compound in the combination unexpectedly enhances the result of the first compound, the enhancement effect is, in some fields, referred to as potentiation.

9.05 Special topics

The following sections set out practice in respect of certain specific topics which give rise to particular considerations with respect to proper disclosure.

9.05.01 Functional limitations

In certain cases, applicants may wish to describe or define an invention using functional language. The use of functional language, whether in a claim or in the description, is not *per se* objectionable. Such language, however, is generally used to provide breadth and must be carefully considered from the perspective of proper support.

Functional limitations must always be considered from the perspective of the person skilled in the art, with the question to be asked being: "can the person skilled in the art practice, in view of the description, the full breadth of the claimed invention without recourse to undue experimentation or inventive ingenuity?" [see 9.02.05]. If the means to effect the defined function are common general knowledge, the functional limitation is unlikely to be objectionable. Where few or only one means is known to effect the function, however, broad functional language would direct the claimed invention to be practised in ways that have not been fully described or enabled and consequently would be objectionable.

Typically, the inquiry into the appropriateness of functional language is driven by the language of the claims. Where an invention is defined in terms of an overly broad functional limitation, the claim seeks to monopolize speculative embodiments that the inventors have not adequately described. The corollary is that the description is not sufficient to support the invention as claimed.

To paraphrase *Free World Trust v. Électro Santé Inc.*, it is not legitimate to invent a particular composition that grows hair on bald men and thereafter claim all compositions that grow hair on bald men.[59]

Thus, a claim to "a composition comprising a hair-growth activating compound in a pharmaceutically acceptable carrier", where only compound X is known to provide the function, would be too broad. The limitation "hair-growth activating" is a functional limitation to the scope of the compounds found in the composition, but does not serve to make the scope of the claim clear to the person skilled in the art. Identifying all the compounds that would have this activity would require extensive inventive experimentation amounting to invention [see 9.02.05]. The description, therefore, is not sufficient to describe and enable the invention asserted in the claim, and is objectionable under subsection 27(3) of the *Patent Act*.

In contrast, if it had been discovered that the combination of a particular drug with any non-steroidal anti-inflammatory (NSAID) compound led to unexpected advantages, functionally limiting the scope of the second component of the composition by the limitation "NSAID" would not be problematic. The scope of the term "NSAID" (or "NSAID compound") would be immediately apparent to the person skilled in the art.

Similarly, in a mechanical invention that relies on a "cutting means", a number of different cutting means would be known to the person skilled in the art. Where it would be readily apparent which would be suitable for operating the claimed invention, the limitation "cutting means" would not improperly broaden the claim. The identification and selection of appropriate cutting means would not require undue effort or further invention in such a circumstance.

9.05.02 Disclosure of biotechnological inventions

Specific disclosure requirements exist for some inventions in the fields of biotechnology. In brief, it may be necessary for a sequence listing of a nucleotide or amino acid sequence to be included with the description or for a deposit of biological material to be made with an International Depository Authority in order for the description of a biotechnology invention to be considered to be sufficient.

Details on the requirements for providing sequence listings or deposits of biological material are provided in sections 17.04.01 and 17.04.02, respectively, of this manual.

9.05.03 The applicant as their own lexicographer

It has long been understood that the language of the claims is to be construed in view of the specification as a whole, and that the applicant can serve as their own lexicographer.

> Their Lordships do not doubt that it is possible for a patentee to make his own dictionary in this way. If he has put something in the earlier part of the specification which plainly tells the reader that for the purpose of the specification he is using a particular word with a meaning which he sets out, then the reader knows that when he comes to the claims he must read that word as having that meaning. But this is an awkward method of drafting and is very undesirable where a simpler method could easily be adopted and it is in all cases incumbent on a patentee who chooses to adopt this method to make his intention plain to those who read the specification.[60]

During examination, the language of the claims is interpreted by giving each term its plain and usual meaning in the art to which the invention pertains, unless it is clear from the description that a term in the claims is to be given a different meaning.

In the context of proper disclosure, it is to be noted that where an applicant, in attempting to act as their own lexicographer, creates a definition for a term that is contrary to the usual meaning ascribed to that term in the art, that is liable to cause confusion or ambiguity, or that is unnecessary in that other plain language could as easily provide the same information, the definition is objectionable. Recall in this context the requirement discussed in 9.02.01 that "[t]he description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and must be as simple and distinct as the difficulty of description permits".

For example, where the description teaches that, for the purposes of the invention, the symbol P (phosphorus) designates nitrogen (elemental symbol N), this definition is only liable to cause confusion and is objectionable under subsection 27(3) of the *Patent Act*. The symbol is recognized in chemistry as designating phosphorus, and could readily be replaced by the appropriate symbol, N, to designate nitrogen.

In contrast, a definition is generally acceptable if, for the purposes of expediency and without sacrificing clarity, it narrows the scope of a term that would otherwise be attributed a broader meaning in the art. In a given case, it might be acceptable to define, for example, that the term "ethylene polymer" means "a non-crosslinked polymer comprising at least 80 mol% ethylene, with up to 20% C_{3-8} alkene comonomer". Providing the longer definition at multiple instances would be unnecessarily cumbersome, and the definition provided unambiguously restricts the broader term.

9.05.04 Disclosure of trade-marked products

An invention may be operated by way of trade-marked products. Simply naming a trade-marked product is not, however, equivalent to describing the composition of that product.

Further, simply knowing what components are included in a trade-marked product does not identify which of those components is an essential element of the invention (i.e. which component or components are necessary to fulfill the trade-marked product's role in the invention). Thus, even though a person skilled in the art may, depending on the state of the art, be able to reverse engineer a trade-marked product and identify its components, this will not by necessity put them in possession of the invention.

Therefore, where an invention is described only in terms of a trade-marked product, the question of proper support must be carefully considered. If it is not clear which component of the product is responsible for the product's role in the invention, the invention cannot be operated other than by the trade-marked product itself.

If the composition of the trade-marked product is not known, and the product is not commercially available, the invention is not enabled.

Where an invention is described in terms of specific components (e.g. chemical compounds), but is supported by examples that rely on trade-marked products of undisclosed composition, no presumption exists that the examples embody the invention described. The applicant must establish that they were aware of the composition of the trade-marked product no later than at the filing date.

Where the composition of a trade-marked product did not form part of the prior art as of the filing date, its composition cannot subsequently be added to the application [see 9.08].

[For requirements regarding the identification of trade-marks, see 9.07.03.]

9.05.05 Description by reference to the claims

The invention must be "correctly and fully" described in the description, which according to section 2 of the *Patent Rules* is "that part of the specification other than the claims". Furthermore, in accordance with section 84 of the *Patent Rules*, the claims shall be fully supported by the description.

It is consequently improper for the description to state the nature of the invention by reference to the claims. Such statements suggest that the description does not "correctly and fully" disclose the invention and does not comply with subsection 27(3) of the *Patent Act*.

Therefore, where the description teaches in some fashion that the invention is "according to the claims", the statement must be removed or replaced by an explicit description of the invention.

By way of example, statements such as "the problem of premature ignition in the combustion chamber is overcome through the method of claim 1" or "the compositions as instantly claimed exhibit superior insecticidal properties" fail to set forth explicitly what the invention in question is, but suggest instead that the invention is whatever might be claimed at any given moment in time.

Note that amending the description to include the language of the claims originally filed is necessarily compliant with subsection 38.2(2) of the *Patent Act*.

9.05.06 Statements expanding the scope of the claims

Since the claims of a patent must be supported by the description, any statement that the claims are to be viewed as broader than the teachings of the description is incorrect and must be removed. Such statements suggest that the description does not "correctly and fully" disclose the invention and does not comply with subsection 27(3) of the *Patent Act*.

A statement such as "the description should be understood as illustrative of the invention, but should not be considered as limiting on the claims appended hereto", which suggests that the description merely sets out certain preferred aspects of the invention and is therefore not limiting of the claims, causes a lack of clarity as to the intended scope of the claims and must be removed.

An indication that the claims encompass or must be interpreted having regard to the "spirit of the invention" is also an attempt to expand the scope of the claims in a vague and undefined way, and must be removed.[61]

In contrast, a statement such as "the scope of the claims should not be limited by the preferred embodiments set forth in the examples, but should be given the broadest interpretation consistent with the description as a whole", which simply notes that the claims are not to be limited to the preferred or exemplified embodiments of the invention, is permissible.

9.05.07 References to foreign practice or law

Where an application includes a statement whose correctness is dependent on foreign patent prosecution practices or laws, such a statement may be inaccurate or liable to cause confusion in the context of Canadian law. Where this is the case, the statement must be removed. The statements may be viewed as being "incorrect", and therefore a defect under subsection 27(3) of the *Patent Act* [see 9.09].

An indication that the application is a continuation-in-part or a divisional of a foreign patent document, for example, is not correct in the context of the Canadian *Patent Act* and must be removed.

A statement regarding the rights of foreign governments to the invention may also be misleading, and should be removed if it is inaccurate.

9.06 Form of the description

The form a description should take is set out in section 80 of the *Patent Rules*.[62] Thus,

> (1) The description shall
>
> (*a*) state the title of the invention, which shall be short and precise and shall not include any trade-mark, coined word or personal name;
>
> (*b*) specify the technical field to which the invention relates;
>
> (*c*) describe the background art that, as far as is known to the applicant, can be regarded as important for the understanding, searching and examination of the invention;
>
> (*d*) describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution;
>
> (*e*) briefly describe the figures in the drawings, if any;
>
> (*f*) set forth at least one mode contemplated by the inventor for carrying out the invention in terms of examples, where appropriate, and with reference to the drawings, if any; and
>
> (*g*) contain a sequence listing where required by subsection 111(1).
>
> (2) The description shall be presented in the manner and order specified in subsection (1) unless, because of the nature of the invention, a different manner or a different order would afford a better understanding or a more economical presentation.

The provisions of subsection 80(2) of the *Patent Rules* would allow, for example, that drawings associated with the prior art be described with the background art, prior to the brief description of the figures in any remaining drawings.

The title of the invention should be descriptive of the invention in suit, and not merely of the field to which the invention pertains. A title such as "flame-retardant rigid polyurethane foam" is acceptable, whereas "foam" is not.[63]

In accordance with paragraph 80(1)(*a*) of the *Patent Rules*, the Office considers the title provided in the description to be the correct title of the invention. Where, for any reason, the title ascribed to the invention in the Office's electronic database differs from the title provided in the description, the electronic database will be updated at the time of grant to reflect the title set out in the description.[64]

Disagreement between the title in the description and the title in the Office's electronic database is not a defect in the application. An examiner may note the existence of such a disagreement, in order to apprise the applicant of the situation and provide them with an opportunity to address the matter. Such a disagreement may also be brought to the applicant's attention subsequent to allowance, by way of an Office letter.

Paragraph 80(1)(*c*) of the *Patent Rules* requires that the applicant describe the background art that, as far as is known to them, is important for the understanding, searching and examination of the invention. Where relevant background art is identified during prosecution, an applicant may, within the limitations imposed by section 38.2 of the *Patent Act* [see 9.08], introduce to the description references to and descriptions of the contents of prior art documents where these are clearly admitted to be prior art with respect to the application. Examiners should, in general, not raise an objection simply because the description has not been amended to identify background art brought to the applicant's attention subsequent to filing.

Paragraph 80(1)(*f*) of the *Patent Rules* provides that, "where appropriate", the applicant must set forth in terms of examples, at least one mode contemplated by the inventor for carrying out the invention. The use of the wording "where appropriate" in this rule reflects that an exemplary basis may or may not be necessary depending on the case at hand. The language "where appropriate" does not merely mean "if the applicant deems it appropriate", and does not provide any exception to the disclosure requirements of subsection 27(3) of the *Patent Act*.

It is not necessary for the description to present the information required by section 80 of the *Patent Rules* in sections bearing headings corresponding to the paragraphs of subsection 80(1), although an applicant may choose to do so for the sake of clarity.

Headings such as "Summary of the Invention", "Detailed Description of the Invention" and "Detailed Description of the Preferred Embodiments" are permitted in Canadian practice. It is worth noting, however, that where a heading such as "Detailed Description of the Preferred Embodiments" is used, support for claims broader than these embodiments must be found in other parts of the description which must satisfy the requirements of subsection 27(3) of the *Patent Act*, including enablement and support for any sound prediction, in respect of the invention as broadly claimed.

9.07 Formalities requirements of the description

The description is subject to many formalities requirements dealing with various aspects of its contents and presentation. These are summarized in the following sections.

9.07.01 Pages of the description

In accordance with subsection 73(1) of the *Patent Rules* the description must be on consecutively numbered pages,[65] and in accordance with section 72 of the *Patent Rules* no page of the description may contain anything belonging to another part of the application.[66]

9.07.02 Drawings, graphics and tables

In accordance with section 74 of the *Patent Rules*, the description shall not contain drawings[67] but may contain chemical or mathematical formulae or the like.[68] For greater clarity, a chemical formula may be presented in the description in graphical form (i.e. as a structure).[69] The description may also contain information presented in tables. In accordance with subsection 75(2) of the *Patent Rules*, any formula or table may, where it aids presentation, be presented sideways (i.e. in landscape format) with the top of the formula or table at the left side of the sheet.[70] Otherwise, subsection 75(1) of the *Patent Rules* provides that pages of the description must be used upright (i.e. in portrait format).[71]

It can be inferred from section 37 of the *Patent Act* that a drawing is an illustration of the invention. Schematics that illustrate a process, such as flow-charts, are generally considered to be drawings.

Graphical representations of data, such as graphs, histograms, pie charts, and spectra, are not necessarily to be viewed as "illustrations of the invention", and therefore may be included in the description. Where a graphical representation of data is provided as a drawing, it must comply with all the requirements of section 82 of the *Patent Rules*.

Tabulated data generally cannot be considered a "drawing", and typically should be presented in the description.

Where the application contains drawings, subsection 82(9) of the *Patent Rules* requires that any reference characters appearing on any figures in the drawings, and only these reference characters, be mentioned in the description.[72] Further, where features are identified by reference characters, subsection 82(10) of the *Patent Rules* requires that the same reference characters must be used throughout the description to refer to those features, and may not be used to refer to any other features.[73]

9.07.03 Identification of trade-marks

In accordance with section 76 of the *Patent Rules*, any trade-mark mentioned in the application shall be identified as such.[74] The Office requires that each trade-mark be identified in an appropriate manner at least once, preferably at its first appearance.

Use of the words "trade-mark" in parentheses, of the designation "™", or of an indicator such as an asterisk (*) linked to a footnote denoting that the asterisk designates a trade-mark are all examples of appropriate manners for identifying a trade-mark in an application.

9.07.04 Identification of documents

In accordance with section 81 of the *Patent Rules*, a document referred to in the description must be available to the public and be fully identified, and shall not be incorporated by reference.[75]

The Office considers a patent document to be properly identified when the country or office code is provided along with a number under which the published version of the document can be found. Thus, the number provided can be that given to a granted patent, or be either the application number or publication number of a published application.

WO 96/937212, US 5,410,288, and EP 1 004 793 are examples of patent documents properly identified by a publication or patent number.

PCT CA2006/001,285 and U.S.S.N. 11/421,399 are examples of application numbers which are acceptable if the identified application has been published.

PCT applications, and US applications filed after November 28, 2000, will generally be published unless the application has been withdrawn (or, in the case of US applications, abandoned) prior to the publication date. Under 35 U.S.C. 122, a US application may also be kept confidential (i.e. will not be published) if the applicant certifies that they will not file an application for the disclosed invention in any other country. Where a US application is relied on as a priority document, this provision does not apply. US provisional applications, applications for design patents, and applications in series 09 or earlier are not necessarily published and may not be referred to by their application numbers unless the document is available to the public.[76]

For non-patent documents, the requirement is that the document be sufficiently well identified to permit it to be obtained by an interested party.

For a journal article, textbook, or the like, the document should be identified by the names of the author and the publication, the year of publication, the volume and/or issue number(s) if applicable, and the page numbers of the article, number of the chapter or the like. Preferably, the title of an article or title of a chapter should be provided. Additional information, such as the name of the publisher, may be included. Where a unique document identifier such as an ISBN code is provided, this does not replace any of the foregoing requirements.

References to internet pages present a particular difficulty in that neither the URL nor the content of such pages is necessarily fixed. Examiners will object to the identification of a document by way of a URL where it is not clear that the URL refers to a reliable, publically available source that can reasonably be expected to ensure the information in question is of fixed content and will be more or less permanently retrievable.

9.08 Amendments to the description

In accordance with subsection 38.2(1) of the *Patent Act*, the description is subject to amendment before grant. Under subsection 38.2(2) of the *Patent Act*, any such amendment may not introduce "matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application" (for convenience, such matter may be referred to simply as "new matter").

Note that one amendment that is always permissible from the standpoint of "new matter" is the inclusion of the language of the originally filed claims in the description.

General guidance regarding the amendment of applications is provided in chapter 19 of the manual.

As regards the description, particular attention must be given to amendments that replace restrictive language with permissive language. Where an application teaches that the invention (as opposed to an embodiment of the invention) "must be" or "is" (or the like) operated in a certain way, amendment of this language to indicate that the invention "preferably" or "optionally" (or the like) is operated in that way enlarges the scope of the invention and may be seen as the addition of new matter.

Similarly, it is possible for the deletion of text to amount to the addition of new matter. If a passage in the description teaches that an invention is inoperative under certain conditions, an amendment to remove this guidance could be viewed as introducing new matter by expanding the scope of the operable invention.

Where a description included both permissive and restrictive language regarding a certain limitation, amending the description to make it self-consistent throughout will generally not be seen as the addition of new matter.

An invention requires an inventive step, and the presence of this inventive step must be evaluated in view of the specification as filed. Amendments that appear to introduce new aspects of “inventiveness” to the application introduce new matter.

Remembering that an invention is a solution to a practical problem, it can be understood that amendments that tend to transform the invention as originally disclosed into a new invention - that is to say, into a new solution to the same or a different problem - constitute the addition of new matter.

Such amendments shift the point of invention and have the effect of causing a different invention to be disclosed than that in the specification as originally filed.

The description may be amended to make reference to prior art documents. Where the amendment is merely to clarify the state of the art, this will generally not be considered to introduce new matter. Where, however, an amendment introduces information from a prior art document, these amendments may, depending on the circumstances, introduce new matter.

Where specific teachings in a prior art document are required in order to enable the invention to be operated, or in order to support a sound prediction of utility, and it would not have been clear to the person skilled in the art, as of the claim date, which teachings in the prior art document were necessary for this purpose, identifying or including the specific teachings constitutes the addition of new matter.

9.09 Office actions on the description

Objections dealing with substantive issues of sufficiency are presented under subsection 27(3) of the *Patent Act*, or a specific paragraph of that subsection where this precision may be helpful in underlining the basis of the objection.

As is the case with objections under subsection 27(4) of the *Patent Act*, however, the defects being objected to under subsection 27(3) can range from significant issues of sufficiency to fairly minor defects of clarity. The presence of a subsection 27(3) objection is not by necessity an indication of any un-remediable defect relating to sufficiency.

Nevertheless, wherever a more specific authority exists on which to base the objection being made, this authority should be used in place of subsection 27(3) of the *Patent Act*. For example, if a reference character has been included in the drawings but is not mentioned in the description, this defect should be presented under subsection 82(9) of the *Patent Rules* rather than under subsection 27(3) of the *Patent Act*.

Objections to formatting or other minor problems are presented under authority of whichever section relates to the defect under consideration [see 9.07 and the related endnotes].

Non-compliance with the formatting requirements set out in sections 68, 69 and 70 of the *Patent Rules* [see section 5.03 of this manual] can be identified by an examiner in order to inform applicants of any defects and expedite advancing the application to allowance. It is not, however, required for an examiner to do so, since correction of these defects can also be requisitioned by examination support staff. It is noted that the Canadian requirements as to formatting are based on those required under the Patent Cooperation Treaty, and requisitioning compliance with the Canadian requirements is therefore permissible under Article 27, PCT.

Endnotes for chapter 9

1. See the definitions of “description” and “claims” in section 2 of the *Patent Rules.*

2. *Apotex Inc. v. Wellcome Foundation Ltd.* 2002 SCC 77 at paragraph 37

3. *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)* [(1989), 25 C.P.R. (3rd), 257 (S.C.C.)] at page 268; *Apotex v. Wellcome* (supra at 2) at paragraph 70; *Electrolytic Zinc Process Co. v. French’s Complex Ore Reduction Co.* [1930] S.C.R. 462 at paragraph 22; *Leithiser v. Pengo Hydra-Pull of Canada Ltd.* [(1974), 17 C.P.R. (2nd), 110 (F.C.A.)] at pages 113-115; *Lundbeck Canada Inc. v. Minister of Health* 2009 FC 146 at paragraph 135; *Pfizer Canada Inc. v. Novopharm Limited* 2009 FC 638 at paragraph 105. See also *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* 2008 SCC 61, e.g. at paragraph 26, applying these requirements to prior disclosures being considered for the purposes of anticipation.

4. *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at pages 154-155, Dickson J. quoting H.G. Fox from his *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.]

5. *Consolboard* (supra at 4) at page 157

6. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)] at page 111

7. *Minerals Separation* (supra at 6)

8. *Minerals Separation* (supra at 6) at pages 111-112, with these points being reasserted by Thurlow J. in *Société des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd. et al.* [(1968), 55 C.P.R. (1st), 207 (S.C.C.)] at pages 225-226; *Wandscheer et al. v. Sicard Limitée* [(1947), 8 C.P.R. (1st), 35 (S.C.C.)] at pages 39-40.

9. This position has been adopted by the courts so often that it has become axiomatic. See, e.g., *Whirlpool Corp. v. Camco Inc.* 2000 SCC 67 at paragraph 53; *Consolboard* (supra at 4) at page 160

10. *Free World Trust v. Électro Santé Inc.* 2000 SCC 66 at paragraph 44, quoting H.G. Fox from his *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.] at page 184; *Whirlpool* (supra at 9) at paragraph 49, citing *Lister v. Norton Brothers and Co.* [(1986), 3 R.P.C. 199 (Ch.D.)] at page 203

11. *Free World Trust* (supra at 10) at paragraph 44

12. From *Beloit Canada Ltd. v. Valmet Oy* [(1986), 8 C.P.R. (3rd), 289 (F.C.A.)] at page 294 we know them to be a "paragon of deduction" and from *Whirlpool* (supra at 9 at paragraph 74) we know them to be "reasonably diligent in keeping up with advances in the field to which the patent relates". See also the comments on point in *Janssen-Ortho Inc. v. Novopharm Limited* 2006 FC 1234 at paragraph 113.

13. *Bayer Aktiengesellschaft v. Apotex Inc.* [(1995), 60 C.P.R. (3rd), 58 (On.Ct.G.D.)] at page 79

14. *Servier Canada Inc. v. Apotex Inc.* 2008 FC 825 at paragraph 99

15. *Servier* (supra at 14) at paragraph 254

16. *Axcan Pharma Inc. v. Pharmascience Inc.* 2006 FC 527 at paragraph 38

17. *Bayer AG* (supra at 13) at page 79; *Johnson & Johnson Inc. v. Boston Scientific Ltd.* 2008 FC 552 at paragraph 97; *Lundbeck Canada Inc v. Minister of Health* 2009 FC 146 at paragraph 36

18. In respect of applications filed on or after October 1, 1996.

19. The comments in *GlaxoSmithKline Inc. v. Pharmascience Inc.* 2008 FC 593 at paragraph 35, while they relate to expert witnesses at trial and not to examiners and inventors/applicants during examination, are illustrative.

20. see, e.g., *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 37; *Burton Parsons Chemical Inc. v. Hewlett-Packard (Canada) Ltd.* [(1976), 17 C.P.R. (2nd), 97 (S.C.C.)] at page 105

21. *Pfizer v. Novopharm* (supra at 3) at paragraph 108; *Sanofi-Aventis Canada Inc. v. Apotex* 2009 FC 676 at paragraph 233; *Free World Trust* (supra at 10) at paragraph 54. Note, however, that the Supreme Court in *Free World Trust* was addressing the date for claim construction rather than enablement.

22. *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 37. During examination, such obvious errors should be corrected whenever identified.

23. *TRW Inc. v. Walbar of Canada Inc.* [(1991), 39 C.P.R. (3rd), 176 (F.C.A.)] at page 197

24. *Procter & Gamble Co. v. Bristol-Myers Canada Ltd.* [(1978), 39 C.P.R. (2nd), 145 (F.C.T.D.)] at pages 159-160, aff'd [(1979), 42 C.P.R. (2nd), 33 (F.C.A.)]; see also

Apotex v. Sanofi-Synthelabo (supra at 3) at paragraphs 33-37

25. *Rice v. Christiani & Nielsen* [1929] Ex.C.R. 111 at paragraph 9, rev'd on other grounds

26. H.G. Fox, *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed., Carswell (Toronto)] at page 171; the last sentence in the first paragraph was quoted with approval in *Pioneer Hi-Bred* (supra at 3) at page 270

27. *Janssen-Ortho Inc. v. Novopharm Ltd.* 2004 FC 1631 at paragraph 54; quoted in *Bristol-Myers Squibb Canada Co. v. Novopharm Ltd.* 2005 FC 1458 at paragraph 71, *Aventis Pharma Inc. v. Apotex Inc.* 2005 FC 1504 at paragraph 126. Note that in the foregoing cases the Courts were addressing the question of obviousness, and whether engaging in routine testing made the result of that testing unobvious. However, the link between the obviousness analysis and the evaluation of sufficiency is addressed in *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.* 2010 FC 230 at paragraphs 57-80. See also the comments in *Pfizer Limited v. Ratiopharm* 2010 FCA 204 at paragraphs 16 to 27.

28. *Pfizer Canada Inc. v. Canada (Minister of Health)* 2006 FCA 214 at paragraph 24

29. *Janssen-Ortho Inc. v. Apotex Inc.* 2008 FC 744 at paragraph 111; *Pfizer v. Canada* (supra at 28) at paragraphs 26 and 27

30. *Apotex* (supra at 2) at paragraph 70

31. *Apotex* (supra at 2) at paragraph 70

32. *Apotex* (supra at 2) at paragraph 37

33. *Norac Systems International Inc. v. Prairie Systems & Equipment Ltd.* 2002 FCT 337 at paragraph 16, rev'd in part on other grounds 2003 FCA 187

34. *Dimplex North America Ltd. v. CFM Corp.* 2006 FC 586 at paragraph 80, aff'd 2007 FCA 278; citing *Norac Systems* (supra at 33)

35. Fox (supra at 26) citing at pages 150-151 *Mullard Radio Valve Company Ltd. v. Philco Radio and Television Corporation of Great Britain Ltd.* [(1935), 52 R.P.C. 261] at page 287; quoted in *Eli Lilly Canada Inc. v. Novopharm Ltd.* 2007 FC 596 at paragraph 188 and in *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.* [(1978), 39 C.P.R. (2nd), 191 F.C.T.D.)] at page 216

36. *Norac Systems* (supra at 33) at paragraph 41; *Almecon Industries Ltd. v. Anchortek Ltd.* 2001 FCT 1404 at paragraph 45, aff'd 2003 FCA 168, citing

Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd. [(1978), 39 C.P.R. (2nd), 191 F.C.T.D.)] at page 216

37. *Metalliflex Ltd. v. Rodi & Wienenberger Aktiengesellschaft* [(1960), 35 C.P.R. (1st), 49 (S.C.C.)] at pages 53-54

38. *Apotex* (supra at 2) at paragraph 46

39. *Pfizer v. Novopharm* (supra at 3) at paragraphs 76 and 82, aff'd 2010 FCA 242 at paragraph 82

40. see, e.g., *Novopharm Limited v. Janssen-Ortho Inc.* 2007 FCA 217 at paragraph 26; *Johnson & Johnson Inc. v. Boston Scientific Ltd.* 2008 FC 552 at paragraphs 376-377; *Pfizer Canada Inc. v. The Minister of Health* 2008 FC 13 at paragraphs 99 and 118

41. *Apotex* (supra at 2) at paragraph 70

42. *Eli Lilly Canada Inc. v. Apotex Inc.* 2009 FCA 97 at paragraphs 10-18; *Eli Lilly Canada Inc. v. Novopharm Limited* 2009 FC 235 at paragraph 101; *Servier* (supra at 14) at paragraph 379

43. *Eli Lilly Canada Inc. v. Apotex Inc.* 2008 FC 142 at paragraphs 163-164; *Eli Lilly v. Apotex* (supra at 42) at paragraph 12

44. *Eli Lilly v. Apotex* (supra at 42) at paragraph 18; this requirement extends equally to any factual basis needed to support a sound prediction of an advantage possessed by a selection from a broader group, see *Pfizer Canada Inc. v. Canada (Minister of Health)* 2008 FC 500 at paragraph 97 and *GlaxoSmithKline* (supra at 19) at paragraph 71

45. *Apotex* (supra at 2) at paragraph 70; *Pfizer Canada Inc. v. Canada (Minister of Health)* 2007 FCA 209 at paragraph 152

46. *Pfizer Canada Inc. v. Apotex Inc.* 2007 FC 26 at paragraphs 66-70; aff'd 2007 FCA 195 - the Court concluded its observations on the patent in suit by noting that "[u]tility and sound prediction are questions of fact and must obviously be supported by evidence."

47. *Servier Canada Inc. v. Apotex* 2008 FC 825 at paragraph 379; *Eli Lilly v. Apotex* (supra at 42) at paragraph 18; *Eli Lilly v. Novopharm* (supra at 42) at paragraphs 101 and 107; *Merck & Co. v. Apotex Inc.* 2005 FC 755 at paragraphs 125-126

48. *I.G. Farbenindustrie A.G.'s Patents* [(1930), 47 R.P.C. 289] at pages 322-323; these criteria appear to have been endorsed in Canada at least as early as 1947 in *Minerals Separation* (supra at 6 at pages 163-164). They were endorsed by the Supreme Court in *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 10.

49. *GlaxoSmithKline* (supra at 19) at paragraph 70 and at paragraph 51 with reference to *Dreyfus and Others Application* [(1945), 62 R.P.C. 125 (H.L.)] at page 133; *I.G. Farbenindustrie* (supra at 48) at page 327

50. *Pfizer Canada Inc. v. Canada* 2006 FCA 214 at paragraph 4

51. *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 9; *I.G. Farbenindustrie* (supra at 48) at page 321

52. *Pfizer Canada Inc. v. Ranbaxy Laboratories Limited* 2008 FCA 108 at paragraph 59; *Eli Lilly Canada Inc. v. Apotex Inc.* 2007 FC 455 at paragraph 89

53. *I.G. Farbenindustrie* (supra at 48) at page 323

54. see, e.g., *Eli Lilly Canada Inc. v. Novopharm Limited* 2009 FC 235 at paragraph 100; *Eli Lilly Canada Inc. v. Novopharm Ltd.* (supra at 35) at paragraph 162; *Ratiopharm Inc. v. Pfizer Limited* 2009 FC 711 at paragraph 179; *Pfizer Canada Inc. v. The Minister of Health* (supra at 40) at paragraphs 115-116; note the similarity to the comments rendered in *Pfizer v. Apotex* (supra at 46) at paragraphs 66 and 69

55. *The King v. American Optical Co.* [(1950), 13 C.P.R. (1st), 87 (Ex.Ct.)] at page 98

56. *The King v. American Optical* (supra at 55)

57. *Lester v. Commissioner of Patents* [(1946), 6 C.P.R. (1st), 2 (Ex.Ct.)] citing at page 3 *British Celanese Ltd. v. Courtaulds Ltd.* [1935] 52 R.P.C. 171 at page 193

58. *Domtar Ltd. v. MacMillan Bloedel Packaging Ltd.* [(1977), 33 C.P.R. (2nd), 182 (F.C.T.D.)] at pages 189-190; *Bergeon v. De Kermor Electric Heating Co.* [1927] Ex. C.R. 181 at paragraphs 29 and 81; *Schmuel Hershkovitz v. Tyco Safety Products Canada Ltd.* 2009 FC 256 at paragraph 148; *Free World Trust* (supra at 10) at paragraph 27

59. *Free World Trust* (supra at 10) at paragraph 32

60. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1952), 15 C.P.R. (1st), 133 (P.C.)] at pages 144-145

61. *Free World Trust* (supra at 10) at paragraph 31

62. Section 80 of the *Patent Rules* applies to applications filed after October 1, 1996. There is no equivalent to this rule for earlier-filed applications.

63. Note that, for applications filed prior to October 1, 1996 and October 1, 1989, respectively, the requirement that an invention have a title are governed by sections 134 and 170 of the *Patent Rules*.

64. This practice was first communicated in the practice notice *Title of Invention* [C.P.O.R. Vol. 137, No. 4, January 27, 2009].

65. This requirement is governed by subsection 135(4) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(4) of the *Patent Rules* for applications filed before October 1, 1989.

66. There is no such requirement in the *Patent Rules* governing applications filed prior to October 1, 1996.

67. This requirement is explicitly governed by subsection 74(1) of the *Patent Rules* for applications filed on or after October 1, 1996, by subsection 135(3) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(3) of the *Patent Rules* for applications filed before October 1, 1989.

68. The permissibility of chemical and mathematical formulae, and the like, is provided by subsection 74(2) of the *Patent Rules* for applications filed on or after October 1, 1996; for applications filed prior to October 1, 1996 this may only be implied by the lack of any proscription to formulae *per se*.

69. The permissibility of such presentation in applications filed on or after October 1, 1996 is implied from subsection 74(2) of the *Patent Rules*. Explicit permission for such presentation is provided by subsection 135(3) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(3) of the *Patent Rules* for applications filed before October 1, 1989.

70. This requirement is governed by subsection 135(2) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(2) of the *Patent Rules* for applications filed before October 1, 1989.

71. This requirement is governed by subsection 135(2) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(2) of the *Patent Rules* for applications filed before October 1, 1989.

72. No such explicit provision exists for applications filed prior to October 1, 1996.

73. This requirement is governed by paragraphs 141(1)(*g*) of the *Patent Rules* for applications filed before October 1, 1996 and by paragraph 177(1)(*g*) of the *Patent Rules* for applications filed before October 1, 1989.

74. This requirement is governed by section 140 of the *Patent Rules* for applications filed before October 1, 1996 and by section 176 of the *Patent Rules* for applications filed before October 1, 1989.

75. These requirements are governed by section 137 of the *Patent Rules* for applications filed before October 1, 1996 and by section 173 of the *Patent Rules* for applications filed before October 1, 1989.

76. Information regarding the publication of US patent documents is provided based on an interpretation of US practice as expressed in the USPTO's *Manual of Patent Examining Procedure*, 8th Ed. (August 2001) as revised July 2008. See, e.g., sections 101 and 103.

Chapter 10
Drawings

10.01 Drawings

Inventions which can be illustrated by means of drawings must be so illustrated in an application for a patent. The role of the drawings is to clarify the principles of the construction of a device rather than to provide particular details of dimensions or relative proportions. The drawings must clearly show all parts of the invention (subsection 37(1) of the *Patent Act*). Known devices may be illustrated by symbols which have a universally recognized conventional meaning provided that no further detail is essential for understanding the subject matter of the invention. Where text matter in the drawings would give a better understanding of the drawings, a single word or a few words may be used. Blank "blocks" in schematic diagrams must be descriptively labelled. Figures in the drawings which illustrate the prior art should be labelled "PRIOR ART".

Each drawing provided must include reference characters corresponding with those in the description, and the Commissioner may require further drawings or dispense with any of them as the Commissioner sees fit (subsection 37(2) of the *Patent Act*).

Whenever drawings are provided in an application, they must conform to the provisions of sections 72, 82 and 83 and subsections 69(2), 71(3), 74(1), 75(2), 86(1) and (2) of the *Patent Rules*. Section 80(2) of the *Patent Rules* permits reference to the drawings before the "Brief Description of the Drawings" when the reference is made in respect of the prior art.

For applications filed in the period beginning on October 1, 1989 and ending on the day before October 1, 1996, see section 141 of the *Patent Rules*.

For applications filed before October 1, 1989, see section 177 of the *Patent Rules*.

10.01.01 Restriction on amendments to drawings

Drawings may be amended at any time up to the time of payment of the final fee, unless the application is under final rejection (subsection 38.2(1) of the *Patent Act* and section 33 of the *Patent Rules*).

Drawings may not be amended to add matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application (subsection 38.2(3) of the *Patent Act*).

Drawings may only be amended by inserting new pages in place of the pages altered by the amendment and shall be accompanied by a statement explaining their nature and purpose (section 34 of the *Patent Rules*).

10.02 Photographs

In any case in which an invention does not admit of illustration by means of drawings but does admit of illustration by means of photographs, the applicant may, as part of the application, furnish photographs, or photocopies of photographs, that illustrate the invention (section 83 of the *Patent Rules*).

Chapter 11
Claims

11.01 Basic requirements

The claims must define distinctly and in explicit terms the subject matter of the invention for which protection is sought (section 27(4) of the *Patent Act*). Patentable claims must define novel subject matter. To be considered novel the whole of subject matter defined by a claim shall not form part of the state of the art. With respect to each claim in an application for patent in Canada the state of the art may be defined generally as everything disclosed in such a manner that it became available to the public in Canada or elsewhere before the **CLAIM DATE**. The **CLAIM DATE** of a claim in a Canadian patent application is the filing date of the application in Canada, unless, priority is claimed on an earlier filed application in Canada or elsewhere. In the latter case, the claim date is the filing date of the earliest application which supports the subject matter of the claim Sections 2 and 28.1 of the *Patent Act* and Chapter 15 for more detail. The claims should also specify in a positive manner all the elements, features, and critical aspects of the invention which are necessary to ensure the result as set forth in the description. Each claim (read with the introduction to the claims) must be restricted to a single sentence.

Claims may be drafted to contain the three following major parts:

1) preamble or introductory phrase
2) transitional phrase
3) body (or purview)

The preamble identifies the category of the invention and may state the purpose of the invention with regard to this category.

Examples:

A machine for waxing paper ...
A composition for fertilizing the soil ...

The transitional phrase joins the preamble to a recitation of the elements of the invention to be protected. It also indicates, in an abbreviated way, whether the recitation is left open or closed to additional elements.

Examples:

> which comprises, comprising, including, having ...
> consisting of, consisting essentially of ...

The body of the claim lists the main elements of the invention, such as, parts of a device, steps of a process or method, ingredients of a composition, or groups in the chemical formula of a compound.

Notwithstanding the above, the Patent Office will accept any form of claim that conforms to section 27(4) of the *Patent Act* and that sets forth an invention in distinct and explicit terms and otherwise conforms to the *Patent Act* and the *Patent Rules*.

For a consideration of claims with respect to the prior art (novelty and non-obviousness) see Chapter 15.

For consideration of claims with respect to utility, operability and non-patentable subject matter (section 2 of the *Patent Act*) see Chapter 16.

11.02 Principles of construction

Claims are the starting point for construing a patent as they define the invention and exclusive right sought. The relevant date for the analysis of a claim is the claim date (see Chapter 15). When construing a claim the essential elements must be determined. However, in order to determine the nature of the invention and the essential elements of the invention, the specification must be construed as a whole. Analysis of a patent is to be determined from the point of view of one skilled in the art, with a mind willing to understand the invention.

Even though claims are construed with reference to the description, reference to the description is only permitted to assist the understanding of terms used within the claims if these terms have a unique meaning. Reference to the description is not permitted for terms that have a plain, common, and unambiguous meaning as these terms would be known to someone of skill within the art, nor is reference to stray phrases within the description considered support for terms within the claims. Furthermore, reference to the description cannot be used to vary the scope of the claims.

The application of these principles can be found in the following: Beecham v Procter Gamble 1982; AT &T v Mitel 1989; Airscal v M&I Heat 1993; Hi-Quail v Rea's Welding 1994; Mobil Oil v Hercules 1994; Cochlear v Cosem; and Almecon v Nutron 1996.

11.03 Clarity

No speculation should be necessary to determine what is covered by each claim. It must not define some parts of the desired monopoly while only alluding to or vaguely mentioning others. If the invention is difficult to claim, due allowance is given for the limitations of language but involved language should not be used when the invention can be claimed simply. Wording should not be so flexible that several interpretations of it are possible, i.e. the claim should not have more than one meaning or be capable of both broad and narrow interpretations.

11.03.01 Antecedents

When an element is referred to in definite terms without having been introduced previously, the claim is objectionable under section 27(4) of the *Patent Act*. An example of this is, "A device for cracking nuts comprising a cup shaped base and a striker element, said lever tripping the hammer at timed intervals". In this claim there are no proper antecedents for "said lever" and "the hammer".

Implied antecedents may be permitted where the word or phrase, by definition, always contains the missing antecedent. For example, a claim beginning with: "A wheel, the axis being..." or "A compound having the formula I..." are acceptable.

11.03.02 Ambiguity in claims

The claims must be framed in distinct and clear language. They should not include vague or equivocal forms of wording which will create doubt. Examples of unclear language are relative terms or expressions such as "thin", "strong", "a major part", "if desired". If such expressions appear in a claim, they must be further defined in clear and distinct terms or be removed from the claim.

The following are some of the most commonly used imprecise terms that may be encountered in claims:

a) "Such as", "Or the like", "For example".
b) "If desired", "When required".
c) "About", "Approximately", "More or less".
d) "Preferably".

Other terms which in certain circumstances may be indefinite are:

a) "Containing as an active ingredient".
b) "Therapeutically effective amount".
c) "A major part".
d) "Of the character described", "As herein described".
e) "At least", "At least one of".
f) "And/or", "Either....or".
g) "An effective amount", "A sufficient amount", "A synergistic amount".
h) "Not being...", "Not having...", "Not requiring...".

Whenever any of the above terms is encountered in a claim, a possibility exists that the claim may not satisfy the requirements of the *Patent Act* and Rules. Specifically, subsection 27(4) of the *Patent Act* and Section 84 of the *Patent Rules* should be considered.

Some of these terms have been considered in decisions by the courts or by Commissioner's decisions.

a) "Containing as an active ingredient"

This phrase should, in some circumstances be refused as being ambiguous and indefinite because "an" implies the presence of other unspecified active ingredients in addition to the one specified in the claim.

Note: This phrase would be acceptable in a claim if "an" is changed to "the" and the other ingredients of the composition are specified while the utility for which the composition is intended is either inherent from the wording of the claim or expressly stated therein (Rohm & Haas v. Commissioner of Patents 30 C.P.R. 113, Ex.C.).

(b) "Therapeutically effective amount"

As was stated in Gilbert v. Sandoz 64 C.P.R. 14, Ex.C., this is an ambiguous term in a claim. The claims in suit included this phrase in conjunction with a particular phenothiazine derivative when produced by specified process claims in association with a pharmaceutical carrier. While it is recognized that the essence of a great many inventions based on compounds for medicinal purposes resides more in the discovery of the unexpected medicinal utility of the compound than in its effective dose, nevertheless, when such a functional statement occurs in a claim, the medicinal utility of the composition of matter must be stated or be inherent from the preamble of the claim.

A particular amount of an active ingredient in combination with another compound (X) may have an entirely different therapeutic value than a very different amount of the same active ingredient in combination with compound X. Therefore, this functional phrase should only be permitted in a composition of matter claim when the utility of the composition of matter is indicated in the claim and provided that the actual amount taught and prescribed in the disclosure is not an important aspect of the invention. This amount may vary over a considerable range apparent to one skilled in the art because of similar known ranges for analogous compounds for the same purpose. However, if the disclosed range is an important feature of the invention or if the invention is only operable within a prescribed range so as to produce the promised results, then of course this disclosed range must be included in all of the independent claims.

(c) "A major part"

This is an acceptable phrase in a claim if it is used in relation to one part of a two- part system where it is clear that it means more than 50%. However, when it refers to one part in a system consisting of three or more parts, it is refused as indefinite because it is not clear if it means a greater percentage than any of the other components or more than 50% of the overall total.

11.03.03 Negative limitations

Claims containing negative expressions such as "not being...", "not having...", "not requiring..." may be objectionable under section 27(4) of the *Patent Act* in that claims should generally set forth what the invention is or does, and not what it is not or does not do, unless there is no positive way to describe it. Sometimes a dependent claim (Chapter 11.06) contains provisions which effectively cancel or negate some of the features of a preceding claim, thus making the dependent claim broader than the preceding claim. This is objectionable under section 87 of the *Patent Rules*.

11.04 Completeness of claims

To define the invention distinctly and in explicit terms, it is required that sufficient elements be recited for operability. The inventive features must appear in each claim . In the case of a composition, a claim must define a minimum of two ingredients, at least broadly. If a claim does not do this, it is objected to as indefinite and contrary to subsection 27(4) of the *Patent Act*.

11.05 Support

A claim must be fully supported by the description as required by section 84 of the

Patent Rules. All the characteristics of the embodiment of the invention which are set forth in the claim must be fully set forth in the description (Section 84 of the *Patent Rules*). However, since the claims included in the application at the time of filing are part of the specification (see definition of specification in section 2 of the *Patent Rules*), any matter in the originally filed claims that was not included in the description as filed may be added to the description.

A claim is objected to for lack of support by the description if the terms used in the claim are not used in the description and cannot be clearly inferred from the description. Terms used in the claims and in the description must be used in the same sense.

11.05.01 Claims referring to description or drawings

It is generally not acceptable for a claim to contain reference to the description or drawings (subsection 86(1) of the *Patent Rules*). However, in some instances, if the claim is complete in itself and can be read and understood without the reference, the claim is acceptable. The claims must not, in respect of the technical features of the invention, rely on references to the description or drawings except where absolutely necessary. In particular, they must not rely on references such as: "as described in the description " or "as illustrated in Figure 3". The following are examples of exceptions:

(a) Claims which include reference numerals

Reference numerals used in the drawings are permissible in a claim provided they are in brackets or parenthesis (subsection 86(2) of the *Patent Rules*), and the claim is otherwise explicit and complete. However, if a claim is not complete without referring to the parts of the drawings identified by numerals in brackets, it must be objected to as contravening subsection 27(4) of the *Patent Act*.

(b) Claims which make reference to charts, tables and graphs

Tabulations in the form of charts often appear in the descriptions of applications. Such tabulations may also be included in the drawings as are graphs, phase diagrams, absorption spectrograms and the like. In circumstances where the nature of the invention is very complex and it is practically impossible or extremely cumbersome to define the scientific relationship of the different factors in a precise and distinguishing manner, without making reference to other parts of the application, then reference to charts, graphs or tables may be permitted in the claims. However, if such a chart or table, for example, is brief and concise, i.e. about 5-10 lines, the applicant may be required to enter it into the claims (subsection 86(1) of the *Patent Rules*).

(c) Reference to particular unconventional disclosed tests

If a test can be accurately defined in a few lines, then it must be included in the claim and a mere reference to such a test as described should not be permitted. However, when such a test is complex and lengthy to describe, for example if it requires more than one page of the description to characterize it, then the applicant may make reference to the test as therein defined rather than reproduce the test in the claim.

(d) Reference to Sequence listings and Biological Deposits

Reference may be made, within a claim, to sequence listing identifier numbers and biological deposit catalogue numbers (subsections 86(3) and (4) of the *Patent Rules*). These procedures are specified in detail in chapter 17 (Biotechnology).

11.05.02 Scope in relation to description

A claim may be as narrow as the applicant wishes within the scope of the invention disclosed. It must not, however, be broader than the invention as described or supported by the description. Furthermore, a claim will fail if, in addition to claiming what is new and useful, it also claims something that is old or useless (Mineral Separation v. Noranda Mines 12 C.P.R. 99; 12 C.P.R. 182; 15 C.P.R. 133).

Each claim must be read giving its words the meaning and scope which they normally have in the relevant art, unless in particular cases the description gives the words a special meaning by explicit definition. If a claim covers subject matter outside the scope of the described invention, it should be objected to for failing to satisfy the provisions of section 84 of the *Patent Rules*.

11.05.03 Ranges not specifically described

When an application includes claims containing a specific limitation with respect to operating conditions, which limitation falls within a broader range described, no objection is made to the narrow claim solely on the grounds that it is not specifically shown in the description or that the description does not indicate the significance of the described range. For example, an application may describe a process carried out within certain temperature limits, e.g. between 500°C and 800°C. No objection is made if some claims are directed to the process carried out between 500°C and 800°C and others to the process carried out at a temperature falling within a smaller range within the described range, e.g. between 650°C and 700°C. However, should the broad claim fall in view of prior art, the narrower claim would also fall unless it can be shown that by restricting the process to the narrower range, a new and unobvious result is obtained.

11.06 Dependent claims

Section 87 of the *Patent Rules* permits a claim to refer to one or more other claims, in order to define an invention more narrowly by adding further characteristics to those already present in the claims to which reference is made. Such a claim is designated as a dependent claim.

Claims are also permitted to refer to other claims or parts of claims of the same or of another category, in order to avoid repeating lengthy definitions already given and to simplify claiming, provided they do not become ambiguous as a result of such dependency, thereby contravening section 27(4) of the *Patent Act*. Such claims however are not dependent claims and section 87 of the *Patent Rules* does not apply. The patentability of the claim referred to does not necessarily imply the patentability of the dependent claim containing the reference. The following example indicates the form of claiming that is acceptable.

Claim 1: A product comprising composition A.

Claim 2: A process for the production of the composition defined in claim 1 comprising reacting B with C.

An objection is made whenever there is uncertainty as to which part of a preceding claim reference is made or whenever a dependent claim of one category, such as a process, contains by reference so many limitations of another category, such as a product, that it becomes difficult to determine which category the claim covers.

A dependent claim usually refers to other claims in its preamble. In view of subsection 87(1) of the *Patent Rules*, a dependent claim must state the additional features claimed. According to subsection 87(3) of the *Patent Rules*, a dependent claim is understood as including all the limitations inherent in the particular claim or claims in relation to which it is considered. When a claim refers to other claims it must only refer to preceding claims and it must do so to by number.

Examples:

Claim 1: The process of reacting A with B in the presence of a catalyst. (acceptable)

Claim 2: The process of reacting A with B in the presence of a metal containing catalyst. (acceptable)

Claim 3: The process of claim 2 in which the catalyst contains iron. (acceptable)

Claim 4: The process of claim 3 in which the catalyst also contains copper. (acceptable)

Claim 5: The process of claim 1, 2, 3, or 4 in which the catalyst also contains zinc. (acceptable)

Claim 6: The process of any one of claims 1 to 5 in which the catalyst also contains cobalt. (acceptable)

Claim 7: The process of any of the above claims in which the catalyst is supported on an inert carrier. (not acceptable)

Claim 8: The process of claim 5 in which the catalyst is supported on an inert carrier. (acceptable)

Claim 9:	The process of claim 6 in which the catalyst is supported on an inert carrier. (acceptable)
Claim 10:	The process of claim 8 or 9 in which the inert carrier is a silica. (acceptable)
Claim 11:	The process of claims 3 and 4 in which the catalyst also contains manganese. (acceptable)

In the examples given above, no objection would be taken to claims 1-6 and 8-10 in view of the provisions of section 87 of the *Patent Rules*. In contrast, claim 7 which does not refer to the preceding claims by number, would, consequently, violate subsection 87(1) of the *Patent Rules* and would therefore be objected to.

The form of dependent claims accepted under section 87 of the *Patent Rules* will be considered acceptable in all applications presently pending in the Patent Office.

11.07 Combinations

A combination is a union of elements or process steps co-operating to produce a unitary and practical result that is not the sum of the known characteristics of the elements or steps.

A patentable combination is one in which the elements or steps cooperate in an unexpected manner or cooperate in a known way to give an unobvious result or effect. If all the requirements of the *Patent Act* and Rules are met, a claim to such a combination can be allowed.

A subcombination is part of a combination. It may be a single element or step of the combination or may, itself, be a combination.

11.07.01 Exhaustive combinations

Claims must not exceed the scope of the invention by going further than the protection to which the inventor is entitled. Generally, an inventor is entitled to claim the invention, be it apparatus, product or method and its immediate and cooperating environment. For example, claims to a new accelerator pump and the carburetor containing it are permitted. Also, claims to a new type of radio tube grid may be permitted with claims to the tube containing the grid. But claims to a new pump in a carburetor which is attached to an engine or claims to a radio receiver accommodating a tube having a new grid would be objected to unless the overall combination produced new and unexpected results, amounting to further invention, that may require restriction under section 36 of the *Patent Act*.

11.07.02 Aggregation

An aggregation is not a true combination. It consists of the juxtaposition of parts that do not cooperate to produce a result that is other than the sum of the results of the parts. The function of an aggregation is the sum of the functions of the parts and its result is the predictable sum of the separate results. A mere aggregation of old parts cannot form the basis of a patentable invention.

Claims are objected to when the inventive matter is claimed in association with other elements and it is clear that there is no invention in the aggregation so resulting apart from the inventive matter itself. An applicant who submits claims to a new radio receiver may not submit claims that further define the receiver in terms of a standard chassis or cabinet housing the receiver. However, a new combination of container and receiver that unexpectedly gives new and useful results may be made the subject of a separate application.

11.08 Product claims

In product claims, the product may be defined in three ways:

(i) By structure. In the chemical field this includes empirical formulae, structural formulae, and chemically acceptable names.

(ii) In terms of the process by which it is made. These are known as product-by-process claims.

(iii) In terms of physical or chemical properties.

A claim that defines a product by a mixture of two or three of these forms is also possible.

The most explicit and definite form of claims for a product defines the product by structure. Since, under subsection 27(4) of the *Patent Act*, the applicant is required to distinguish any new product from all other products by claiming it distinctly and explicitly, the structure, if known, should be given in the claim.

11.08.01 Product-by-process claims

A product-by-process claim defines the claimed product wholly or partly in terms of the process used to produce the product. The process limitations may be included within the product claim itself or the whole claim may be made dependent upon another claim directed to the process. The following examples show the two possible forms:

(i) The product made by heating A with B.

(ii) The product when made by the process of claim 1.

The use of past participle adjectives, such as welded, bent, molded or coated, is not construed as changing a product claim into a product-by-process claim.

A product-by-process claim, where permitted, must define the product explicitly and distinguish it from all other products. Hence, products that are already known may not be claimed by making them dependent on a new process (Hoffman-La Roche v. Commissioner of Patents 23 C.P.R. 1).

A product-by-process claim must be directed to the final product of the process claim upon which the product claim is made dependent.

11.09 Means claims

A "means" claim is one in which at least part of an invention is defined as a means or mechanism for performing an act, instead of reciting the element that performs the action.

Invention may exist in a new combination of old means (Lightning Fastener v. Colonial Fastener 51 RPC 349; Martin and Biro Swan v. H. Millwood 1956 RPC 125). Claims composed of more than one statement of old means are allowable, without defining structure, if there is invention in the new combination.

If a claim is composed of a single statement of means, it is objected to for being indefinite and contrary to subsection 27(4) of the *Patent Act*. The report of the examiner should indicate in detail why the claim contravenes subsection 27(4) of the *Patent Act*. It may, for example, be directed to the result desired rather than to the combination developed and illustrated to achieve that result.

A claim is also objected to if it contains a broad means statement at the point of invention, i.e., a statement that distinguishes the claim from the prior art, but which is so broad that it embraces all possible means without qualification for solving the problem facing the inventor and is in effect no more than a restatement of the problem or desired result.

Examples:

An application describes a sanding device that may be used in a direct-drive mode for removing stock from a work piece at a rapid rate or in an orbital mode for removing stock at a much slower rate to provide a smooth finish. The invention lies in the combined use of a known one-way clutch and a known reversible motor in an otherwise conventional rotary sander. Under prior art conditions, either two sanders were used or an attachment was employed to convert a device from a direct-drive sander to an orbital sander.

Claim (i) Means for operating a sanding device in either a direct-drive mode or an orbital mode.

This claim would be objected to under section 27 of the *Patent Act*. The applicant should claim a sander having the combination of a one-way clutch with a reversible motor.

Claim (ii) A surface-finishing device comprising a drive shaft, a driven element connected to receive drive from the drive shaft, a driven shaft mounted for rotation in said driven element about an axis eccentric to the axis of the drive shaft, means connecting the driven shaft to the driven element, a surface-finishing tool connected to be driven by the driven shaft, and automatic means for selectively connecting the surface-finishing tool directly to the drive shaft, or allowing said tool to rotate freely in an orbital path about the drive shaft axis.

This claim would be objected to for merely restating the desired result.

Claim (iii) A surface-finishing device comprising a drive shaft, a driven element connected to receive drive from the drive shaft, a driven shaft mounted for rotation in said driven element about an axis eccentric to the axis of the drive shaft, one-way clutch means connecting the driven shaft to the driven element, a surface-finishing tool connected to be driven by the driven shaft, and means for selectively driving the drive shaft in one direction or in an opposite direction.

This claim would be accepted as a novel combination of known means giving a new and unexpected result.

11.10 Process, method, method of use and use claims

The Patent Office accepts process, method, method of use and use claims as explained under the following subheadings.

11.10.01 Process and method claims

A method is the series of steps to be followed either alone or in conjunction within a process in order to achieve a desired result. A method should be distinguished from a process, which includes the method and the substances to which it is applied. The overall process may be new even though the method is old.

A claim to a process which consists of applying a known method to chemically react known substances is patentable, providing the method has never before been applied to these substances and results in new, useful and unobvious products. (Ciba Ltd. v. Commissioner of Patents 27 C.P.R. 82; 30 C.P.R. 135).

11.10.02 Method of use and use claims

When a claim to a compound has been found allowable in an application, then a claim to a method of use of that compound or a claim to the use of that compound is also allowable in the same application. When a claim to a compound has been found allowable to the inventor in one application, then claims in a different application of the same inventor to a use of that compound or methods of using that compound which are obvious from the utility disclosed for the compound, and upon which utility the patentability of the compound was predicated, are not allowed.

When a compound has been patented previously or is in the public domain, claims directed to the obvious use of this compound should be objected to for lacking patentable subject matter. Claims directed to a new and unobvious use of the same compound are allowable. Likewise, claims directed to a method of using the compound for a new unobvious purpose are allowable. Furthermore, when an invention is directed to a novel and unobvious use of a known compound, claims to this known compound with the further recitation of a novel use are allowable (re application for patent of Wayne State University 22 C.P.R. (3d) 407).

When a device or machine is only a new instrument for carrying out an old method, only the device or machine can be patented. Since the utility of a device or machine is obvious from the description of the device or machine, the patentability of a method using such device or machine is determined by the state or the art.

Guidelines for method of use claims

(i) Method of use claims directed to medicinal use are rejected under Section 2 of the *Patent Act* in view of Tennessee Eastman v. Commissioner of Patents (1970) 62 C.P.R. 117; (1974) S.C.R. 111.

Example: Method of treating the symptoms of cognitive decline in a patient comprising administering to a patient an effective amount of compound X wherein said compound is used as a cholinergetic agent. (rejected)

(ii) Method of use claims directed to a medicinal treatment should be interpreted to include only those methods directed to curing or preventing diseases in humans or animals. Method claims directed to an industrial use should not be rejected.

Example: Method for enhancing the dressed carcass weight of meat-producing animals by increasing lean meat deposition and improving the lean meat to fat ratio comprising administering to said animals, before slaughter, either orally or parenterally, an effective amount of a compound X. (accepted)

(iii) Other types of method of use claims directed to an industrial use are allowable but must include manipulative steps. (The reasoning for the requirement of the presence of manipulative steps is to distinguish method of use claims from use claims.)

Example: Method of using compound X as an intermediate to prepare compound Y wherein compound X is reduced by hydroboration or catalytic hydrogenation. (accepted)

(iv) Method of use claims incorporating a use are also acceptable as long as they meet the requirement of a proper method claim (i.e., include a manipulative step). (accepted)

Example: Method of controlling agricultural bacteria which comprises incorporating into the locus to be treated an effective amount of compound X wherein said compound is used as a bacterial agent. (accepted)

(v) Similarly, product claims containing either a use or method definition are acceptable, provided that the method is not a method of medical treatment).

Example: Compound X for the use as an insecticide wherein said compound is applied to the locus of a tree trunk, (accepted).

Example: Compound Y for the treatment of viruses wherein said compound is administered to a patient intravenously, (not accepted because it contains a method of medical treatment).

Guidelines for use claims

(i) Use claims are permitted. Moreover, use claims incorporating method steps are acceptable as long as the use has been clearly identified and it is not a method of medical treatment. If the claim is complete and understandable without the method steps, then the claim as a whole is acceptable. The method steps merely provide a restriction to the previously recited use.

Example: Use of compound X as a herbicide. (accepted)

Use of compound X as a herbicide wherein an effective amount of the compound X is incorporated into the locus to be treated. (accepted)

Use of compound Y as an antiarrhythmic agent. (accepted)

Use of compound Y as an antiarrhythmic agent wherein an effective amount of the compound Y is administered to a patient. (not accepted). The addition of the "wherein" clause makes the use a method of medical treatment.

Use of machine Z for cutting. (accepted)
Use of machine Z for cutting wherein ... (accepted)

11.11 Markush claims

In chemical cases, a claim directed to a genus expressed as a group consisting of certain specified materials is allowable (Ex parte Markush 1925, 340 U.S.O.G. 839) provided it is clear from the known nature of the alternative materials or from the prior art that the materials in the group possess at least one property in common which is mainly responsible for their function in the claimed relationship. Therefore, a Markush claim will generally be construed with a generic expression covering a group of two or more different materials (elements, radicals, compounds) as illustrated in the following examples:

> A solvent selected from the group consisting of alcohol, ether and acetone...
>
> A strip of a conductive metal selected from the group consisting of copper, silver and aluminium...

Occasionally, the Markush format may be used in claims directed to subject matter in the mechanical or electrical fields in a manner such as that illustrated in the example below:

> A means for attaching a wall panel to a framework wherein the attaching means is **selected from group consisting of** nails, rivets **and** screws...

11.12 Selection patents

A selection from members of a previously known class of substances may be patentable if the substance selected is unobvious and affords a new and useful result. There must be a special advantage arising from the selected substance and any advantage, novel property or use must be fully characterized in the description. The substance should be defined in an explicit manner within the claim.

11.13 Jurisprudence

The following decisions of the courts are of importance in considering the subject matter of this chapter:

claims construction

Mineral Separation v Noranda	12 CPR	99	1950
	69 RPC	81	1952

O'Cedar v Mallory Hardware	ExCR	299	1956
McPhar v Sharpe	35 CPR	105	1960
Metalliflex v Wienenberger	35 CPR	49	1961
	SCR	117	1961
Lovell v Beatty	41 CPR	18	1962
Burton Parsons v Hewlet	1 SCR	555	1976
Xerox v IBM	33 CPR (2d)	24	1977
Cutter v Baxter Travenol	68 CPR (3d)	179	1983
Johnston Controls v Varta	80 CPR (2d)	1	1984
Reading & Bates v Baker	18 CPR (3d)	181	1987
AT&T Tech v Mitel	26 CPR (3d)	238	1989
Energy v Boissonneault	30 CPR (3d)	420	1990
Lubrizol v Imperial Oil	33 CPR (3d)	11	1990
	45 CPR (3d)	449	1992
Computalog v Comtech	32 CPR (3d)	289	1990
	44 CPR (3d)	77	1992
Procter & Gamble v Kimberly	40 CPR (3d)	1	1991
Welcome v Apotex	39 CPR (3d)	289	1991
TRW Inc v Walbar	39 CPR (3d)	176	1991
Martinray v Fabricants	14 CPR (3d)	1	1991
Reliance v Northern Tel	47 CPR (3d)	55	1993
Airseal v M&I Heat	53 CPR (3d)	259	1993
Dableh v Ont Hydro	50 CPR (3d)	290	1993
Unilever v Procter & Gamble	47 CPR (3d)	479	1993
	61 CPR (3d)	499	1995
Nekoosa v AMCA Int	56 CPR (3d)	470	1994
Anderson v Machineries	58 CPR (3d)	449	1994
Pallmann v CAE	62 CPR (3d)	26	1995
Hi-Quail v Rea's Welding	55 CPR (3d)	224	1994
Feherguard v Rocky's	53 CPR (3d)	417	1994
	60 CPR (3d)	512	1995
Cochlear v Coseum	64 CPR (3d)	10	1995
Pallmann v CAE	62 CPR (3d)	26	1995
Almecon v Nutron	65 CPR (3d)	417	1996

positive recitation

Mineral Separation v Noranda	12 CPR	99	1950
	69 RPC	81	1952
Burton Parsons v Hewlet	1 SCR	555	1976
Eli Lilly v O'Hara	20 CPR (3d)	342	1988
	26 CPR (3d)	1	1989
Hi-Quail v Rea's Welding	55 CPR (3d)	224	1994
Pallmann v CAE	62 CPR (3d)	26	1995

antecedents

Mobil Oil v Hercules	57 CPR (3d)	488	1994
	63 CPR (3d)	473	1995

preamble

Re: Lelke	72 CPR (2d)	139	1981
Shell Oil v Comm of Pat	2 SCR	536	1982
Rucker V Gavels Vulcanizing	7 CPR (3d)	294	1985
Permacon v Enterprises	19 CPR (3d)	378	1987
Re: Neuro Med Inc	28 CPR (3d)	281	1988
Computalog v Comtech	44 CPR (3d)	77	1992

explicit, distinct v ambiguous/several interpretations

Rohm & Haas v Comm of Patents	30 CPR	113	1959
Xerox v IBM	33 CPR (2d)	24	1977
Monsanto v Comm of Pat	42 CPR (2d)	161	1979
	2 SCR	1108	1979
Ciba Geigy v Comm of Pat	65 CPR (3d)	73	1982
Pioneer Hi-Bred v Com of Pat	14 CPR (3d)	491	1987
	25 CPR (3d)	257	1987
Reliance v Northern Tel	28 CPR (3d)	397	1989
	44 CPR (3d)	161	1992
	47 CPR (3d)	55	1993
Risi Stone v Groupe Peracon	29 CPR (3d)	243	1990

	65 CPR (3d)	2	1995
Allied v Du Pont	52 CPR (3d)	351	1993
	50 CPR (3d)	1	1993
Mobil Oil v Hercules	57 CPR (3d)	488	1994
	63 CPR (3d)	473	1995

insufficient/sufficient/essential elements

BVD Co V Canadian Celanese	ExCR	139	1936
	SCR	221	1937
Mineral Separation v Noranda	12 CPR	99	1947
	15 CPR	133	1952
Curl Master v Atlas Brush	SCR	514	1967
Burton Parsons v Hewlet	1 SCR	555	1976
Re: Farbwerke Hoechst	13 CPR (3d)	212	1980
Ciba Geigy v Comm of Pat	65 CPR (3d)	73	1982
Consolboard v MacMillan	56 CPR (2d)	145	1981
	1 SCR	504	1981
Ductmate v Exanno	2 CPR (3d)	289	1984
Amfac Foods v Irving Pulp	12 CPR (3d)	193	1986
Crila Plastics v Ninety Eight	10 CPR (3d)	226	1986
	18 CPR (3d)	1	1987
Reliance v Northern Tel	28 CPR (3d)	397	1989
	44 CPR (3d)	161	1992
	47 CPR (3d)	55	1993
TRW Inc v Walbar	39 CPR (3d)	176	1991
Atlas v CIL	41 CPR (3d)	348	1992
Airseal v M&I Heat	53 CPR (3d)	259	1993
Mobil Oil v Hercules	57 CPR (3d)	488	1994
	63 CPR (3d)	473	1995
Feherguard v Rocky's	53 CPR (3d)	417	1994
	60 CPR (3d)	512	1995

operability

Union Carbide v Trans Canadian	ExCR	884	1965

Mineral Separation v Noranda	12 CPR	99	1950
	69 RPC	81	1952
Gilbert (Gillcross) v Sandoz	64 CPR	14	1970
	SCR	1336	1974
Burton Parsons v Hewlet	1 SCR	555	1976
Sandvick v Windsor	8 CPR (3d)	433	1986
Mahurkar v Vas-Cath	18 CPR (3d)	417	1988
Welcome v Apotex	39 CPR (3d)	289	1991
TRW Inc v Walbar	39 CPR (3d)	176	1991
Feherguard v Rocky's	53 CPR (3d)	417	1994
	60 CPR (3d)	512	1995
Mobil Oil v Hercules	57 CPR (3d)	488	1994
	63 CPR (3d)	473	1995

broad

BVD Co V Canadian Celanese	ExCR	139	1936
	SCR	221	1937
Trubenizing v John Forsyth	2 CPR	1	1943
O'Cedar v Mallory Hardware	ExCR	299	1956
Lovell v Beatty	41 CPR	18	1962
Boehringer v Bell-Craig	39 CPR	201	1962
Union Carbide v Trans Canadian	ExCR	884	1965
Hoechst v Gilbert	SCR	189	1966
Gilbert v Sandoz	64 CPR	14	1970
Burton Parsons v Hewlet	1 SCR	555	1976
Monsanto v Comm of Pat	42 CPR (2d)	161	1979
	2 SCR	1108	1979
Re: American Home Products	55 CPR (2d)	238	1980
Re: Farbwerke Hoechst	13 CPR (3d)	212	1980
Cutter v Baxter Travenol	50 CPR (2d)	163	1980
	68 CPR (3d)	179	1983
Johnston Controls v Varta	80 CPR (2d)	1	1984
Sandvick v Windsor	8 CPR (3d)	433	1986
Amfac Foods v Irving Pulp	12 CPR (3d)	193	1986
Cabot Corp v 318602 Ont	20 CPR (3d)	132	1988

Mahurkar v Vas-Cath		18 CPR (3d)	417	1988
Reliance v Northern Tel		28 CPR (3d)	397	1989
		44 CPR (3d)	161	1992
		47 CPR (3d)	55	1993
		55 CPR (3d)	299	1994
Risi Stone v Groupe Peracon		29 CPR (3d)	243	1990
Lubrizol v Imperial Oil		33 CPR (3d)	1	1990
		45 CPR (3d)	449	1992
Welcome v Apotex		39 CPR (3d)	289	1991
Dableh v Ont Hydro		50 CPR (3d)	290	1993
Unilever v Procter & Gamble		47 CPR (3d)	479	1993
		61 CPR (3d)	499	1995
Mobil Oil v Hercules		57 CPR (3d)	488	1994
		63 CPR (3d)	473	1995
Nekoosa v AMCA	Int	56 CPR (3d)	470	1994
Pallmann v CAE		62 CPR (3d)	26	1995
Almecon v Nutron		65 CPR (3d)	417	1996

selection/improvement

Sherbrooke v Hydrolic	Ex CR	114	1927
Bergeon v De Kermor	Ex CR	181	1927
Western Electric v Bell	Ex CR	213	1929
Wandscheer v Sicard	SCR	1	1948
K v Uhleman Optical	Ex CR	142	1950
	1 SCR	143	1952
O'Cedar v Mallory Hardware	Ex CR	299	1956
Ciba Geigy v Comm of Pat	27 CPR	82	1957
	30 CPR	135	1959

aggregation/combination

Lightning Fastener v Colonial	Ex CR	89	1932
	SCR	63	1933
	51 RPC	349	1934
Crosley Radio v CGE	SCR	551	1936

Lanlois v Roy	Ex CR	197	1941
Lester v Comm of Pat	Ex CR	603	1946
Wandscheer v Sicard	Ex CR	112	1946
	SCR	1	1948
R v Uhleman Optical	Ex CR	142	1950
	1 SCR	143	1952
Defrees v Dominion Auto	Ex CR	331	1963
Barton v Radiator Specialty	44 CPR	1	1965
Gibney v Ford	2 Ex CR	279	1972
Rubbermaid v Tucker Plastics	8 CPR (2d)	6	1972
Agripat v Comm of Patents	52 CPR (2d)	229	1977
Domtar v MacMillan	33 CPR (2d)	182	1977
Xerox v IBM	33 CPR (2d)	24	1977
Ductmate v Exanno	2 CPR (3d)	289	1984
Windsurfing v Triatlantic	3 CPR (3d)	95	1984
Hy Kramer v Lindsay	9 CPR (3d)	297	1986
Crila Plastics v Ninety Eight	10 CPR (3d)	226	1986
	18 CPR (3d)	1	1987
Hoffman-La Roch v Apotex	15 CPR (3d)	217	1987
	24 CPR (3d)	289	1989
Standal v Swecan	28 CPR (3d)	261	1989
Imperial Tobacco v Rothmans	47 CPR (3d)	188	1993

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Chapter 12
Subject-Matter and Utility

12.01 Scope of this chapter

As was noted by the Supreme Court in *Apotex v. Wellcome*, the granting of patents is "a method by which inventive solutions to practical problems are coaxed into the public domain".[1] To be patentable, an invention must "fulfil the statutory requirements of novelty, ingenuity and utility".[2]

The *Patent Act*, however, is not intended to cover all fields of human endeavour. Those fields to which it applies are called "statutory" and those to which it does not apply are called "non-statutory".

The definition of the term "invention" is set out in section 2 of the *Patent Act* and encompasses, explicitly or implicitly, all the foregoing requirements. The requirements of novelty and ingenuity are more specifically addressed by sections 28.2 and 28.3 of the *Patent Act*, and are discussed in chapter 15 of this manual - "Requirements for Patentability".

The present chapter sets out the Office's practice for determining whether or not an invention is statutory and useful. The former requirement can be framed in terms of asking whether or not the invention is proper "subject-matter" for a patent.

12.02 Statutory subject-matter

The definition of "invention" given in section 2 of the *Patent Act* indicates that an invention is:

> *any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.*

In order to be eligible for patent protection, the matter for which protection is sought must fall within one of the categories of subject-matter defined in section 2 of the *Patent Act*.

12.02.01 Art

The term "art", for the purposes of the *Patent Act*, pertains to the application of knowledge to effect a desired result.[3] To be statutory, an "art" must belong to a field of technology and, consequently, be what the courts have termed a "useful art"[4] and a "manual or productive art".[5]

An art must be the practical application of knowledge,[6] and must therefore be defined in a manner that gives practical effect to the knowledge. An art, therefore, is claimed as either a method or a use.

A statutory "method" must be an act or series of acts performed by some physical agent upon some physical object and producing in that object some change of either character or condition.[7, 8] Whether or not a method is statutory is not determined by whether or not it produces a statutory product.

A "use" is the application of certain means to achieve a specific result. A "use" differs from a "method" in that the contribution to the art must not be resident in the act or series of acts by which the result is achieved, but rather must arise solely from the recognition that the certain means can be applied (in an obvious way) to achieve the specific result [see 12.06.08 for further guidance on "use" claims].

12.02.02 Process

A "process" implies the application of a method to a material or materials,[9] and a statutory process must by necessity apply a statutory method. A process can be considered to be a mode or method of operation by which a result or effect is produced by physical or chemical action, by the operation or application of some element or power of nature or one substance to another. As with methods, whether or not a process is statutory is not determined by whether or not it produces a statutory product.

12.02.03 Machine

A "machine" is the mechanical embodiment of any function or mode of operation designed to accomplish a particular effect. A machine can be considered to be "any device that transmits a force or directs its application" or "a device that enables energy from one source to be modified and transmitted as energy in a different form or for a different purpose".[10]

12.02.04 Manufacture

The term "manufacture" was defined in *Harvard College v. Canada (Commissioner of Patents)* as being, broadly, "a non-living mechanistic product or process" and as being the process of making (by hand, by machine, industrially, by mass production...) technical articles or material (in modern use on a large scale) by the application of physical labour or mechanical power; or the article or material made by such a process.[11]

12.02.05 Composition of matter

The category "composition of matter" refers to combinations of ingredients, whether combined as a chemical union or a physical mixture, and includes chemical compounds, compositions and substances. The term "matter" implies that the ingredients must be perceptible in space and have mechanical mass. In *Harvard College v. Canada (Commissioner of Patents)*, the Supreme Court noted that the scope of this category must be limited in some way, else the categories of "machine" and "manufacture" would be made redundant.[12]

12.03 Inventions must take a practical form

As noted in 12.01, an invention is a solution to a practical problem. In order to solve a practical problem, the solution must be in a form that can interact directly with the physical world and, hence, that will itself enable a person skilled in the art to obtain the intended result or benefit. Such a form is referred to herein as a "practical form" or a "practicable form".

The solution provided by an invention is that set of elements that are necessary to together provide the promised result. To be a "practical form", at least one of these "essential elements" must be physical. For the "practical form" to be statutory subject-matter, the set of "essential elements" must be, when considered in combination, a statutory art, process, machine, manufacture or composition of matter. To be patentable, this "practical form" must also be novel and unobvious; it must have been contributed by the inventors. [See also section 13.05.03 of this manual.]

12.03.01 Ideas are not inventions

The disembodied idea, concept or discovery that underlies or leads to an invention is not itself patentable, but must first be made into an invention by being reduced to a practical form. An idea or concept, no matter how well it may have been worked out and structured in the mind, is disembodied and is not capable of interacting with the physical world to solve a practical problem.

This distinction between a disembodied idea and an invention has been commented on by the courts. In *Shell Oil Co. v. Commissioner of Patents*, for example, the Supreme Court noted that "a disembodied idea is not per se patentable. But it will be patentable if it has a method of practical application".[13] In *Riello Canada Inc. v. Lambert*, the court cited with approval comments from the UK case *Reynolds v. Herbert Smith & Co., Ltd.*, which noted that "the idea that leads to an invention is [...] no part of the invention. The idea, or the recognition of the want, stimulates the inventor to do something else. It is the something further which he does which is the invention" and similarly that "discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen. Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result".[14]

12.03.02 Claiming a practical form

In accordance with subsection 27(4) of the *Patent Act*, a claim must define "subject-matter of the invention". It follows from the foregoing that a claim must define a practical form. More particularly, this practical form must be either a physical object (a machine, article of manufacture or composition of matter) or an art or process in a field of technology that is practised as an act or series of acts performed by some physical agent upon some physical object to produce in that object some change of either character or condition (hereafter, such acts are referred to as physical steps).

Where a claim defines subject-matter that is disembodied, it necessarily follows that the matter of the claim is not statutory [see 12.03.01]. Where a claim does define at least one physical object or physical step, it may nevertheless be that the claim does not define a statutory invention. This could be either because an embodiment encompassed by the claim is excluded or because the contribution made by the inventors does not include any physical object or step defined in the claim. Section 13.05.03 of this manual provides guidance on the manner of assessing the contribution, and sections 12.05 and 12.06 of this chapter provide specific guidance on how certain subject-matter is to be examined in the context of section 2 of the *Patent Act* and the contribution analysis.

12.04 Inventions must relate to fields of technology

The Courts have described the *Patent Act* as applying to the "useful arts" and the "manual and productive arts". The Office considers these terms to refer, in language more reflective of modern industry, to "fields of technology" [see 12.02.01]. An invention that does not relate to a "field of technology" is by consequence not statutory.

The term "technology" means "the application of scientific knowledge for practical purposes, especially in industry", "machinery and equipment developed from scientific knowledge", and "the branch of knowledge dealing with engineering or applied sciences".[15]

The "practical form" of a statutory invention [see 12.03] must therefore be a technological solution to a practical problem [see section 13.05.01*a* of this manual].

12.04.01 Relationship of claimed matter to a field of technology

As discussed in section 13.05.02 of this manual, examination of claims is performed from the perspective of both form and substance, and the requirement that an invention relate to a field of technology may, as appropriate, be evaluated in respect of both the form and substance of a claim.

In terms of form, a claim that, by its language, defines a “machine”, “manufacture” or “composition of matter”, is directed in form to statutory matter.

The category “manufacture” has been interpreted in such a fashion that it relates to both the manner of producing a product and to the product. A manner of producing “technical articles or material” [see 12.02.04] is statutory, and could be viewed as coming within the category “art”, “process” or “manufacture”. Regardless, such a manner of production falls within the definition of “field of technology”.

An “art” or “process” that does not produce a technological article or material, however, may define by its form either statutory or non-statutory subject-matter. A claim that defines an art or process that has as its ultimate object the solution of a problem outside a field of technology is non-statutory by its form, whether or not it relies on patentable technology to achieve its purpose.

Thus, an artistic method for painting a portrait is non-statutory, and this does not depend on whether or not a patentable paintbrush or paint is used in the method [see 12.06.03]. Similarly, a method for swinging a golf club is non-statutory regardless of whether or not the club being swung is patentable in its own right [see 12.06.05].

Where a claim defines subject-matter that is not objectionable by its form, it remains that the claim must define an “invention” in substance in order to be patentable. That is, a statutory “practical form” must have been contributed and the claimed subject-matter must be or include this novel and unobvious set of “essential elements” [see 12.03].

Consider, for example, a claim to a toy soldier covered with a paint that changes colour in response to pressure, or to a novelty toy which rotates about an axle. Each toy falls into the category “manufacture”, and in form is statutory. The toys, of course, are for entertainment, and serve no practical purpose related to industry. They are not themselves technological solutions to any problem in a field of technology. The patentability of the toys will therefore depend on their including a technological solution to such a problem. For example, developing the particular pressure-sensitive paint or figuring out how to enable the paint to be successfully applied to the toy could be a novel and inventive technological solution to a problem in a field of technology. Similarly, if the novelty toy was improved by the provision of an axle assembly having reduced friction, and thus allowing for better motion about the axle, the toy as a whole would include a technological solution (the axle assembly).

12.04.02 Guidance on non-technological fields

As noted above, an "art" or "process" that addresses a problem in a non-technological field is, itself, non-statutory.

Fields of human endeavour such as economics, commerce, accounting, record-keeping, marketing, and law are not themselves fields of technology. While it is certainly possible for inventions of relevance to such fields to be patentable (i.e. tools for use in their practice), advances in the concepts of their practice are beyond the scope of section 2 of the *Patent Act*. This exclusion applies to many types of commercial interactions, and in some contexts can be descriptively referred to as a "business method" exclusion as was done in *Re Application No. 2,246,933 of Amazon.Com.*[16]

Methods for influencing human interactions or behaviours do not belong to a field of technology. Such methods are implicitly dependent on the subjective interpretations, judgements and value systems of the parties involved, and these are not in any practical sense subject to the laws of science. It can therefore be broadly stated that methods of interpersonal communication and interactions governed by subjective valuations are not statutory. This includes methods for teaching, bartering, trading, selling, advocating, lobbying, etc.

Similarly, methods that are significant only by virtue of human, rather than natural, law do not belong to a field of technology. Thus, a method for filing taxes or for engaging in binding arbitration is not statutory.

12.05 Excluded subject-matter

It has long been appreciated that "[t]here is no inherent common law right to a patent. An inventor gets his patent according to the terms of the *Patent Act*, no more and no less".[17]

It is apparent from the form of the section 2 definition of "invention" that not everything can be patented. The Supreme Court noted in *Harvard College v. Canada (Commissioner of Patents)*,[18] in respect of this definition, that "[b]y choosing to define invention in this way, Parliament signalled a clear intention to include certain subject matter as patentable and to exclude other subject matter as being outside the confines of the Act". In her comments in *Monsanto Canada Inc. v. Schmeiser*, Arbour J. likewise noted that "[c]laims that would otherwise be valid may be limited by statutory provisions or by jurisprudence".[19]

The following sections set out various statutory and jurisprudential proscriptions to the scope of patentable subject-matter. The matter of any of the following sections is objectionable when claimed *per se* or when defined in a claim which includes no contributed statutory subject-matter [see section 13.05.03*b* of this manual].

12.05.01 Scientific principles and abstract theorems

Subsection 27(8) of the *Patent Act* indicates that

> *No patent shall be granted for any mere scientific principle or abstract theorem.*

This subsection has been interpreted as proscribing from patentability (*inter alia*) mathematical formulae,[20] natural phenomena and laws of nature.[21]

The proscriptions of this subsection apply when an attempt is made to monopolize the excluded subject-matter in a general sense, but not when (e.g.) a scientific principle, law of nature or mathematical formula is relied on in operating a practical form of an invention.

12.05.02 Methods of medical treatment or surgery

A method which provides a practical therapeutic benefit to a subject is considered to be a method of medical treatment and is therefore not patentable.[22]

By way of example, medical, surgical, dental, and physiotherapeutic methods of treatment are all excluded matter. To be considered a method of medical treatment, the method should cure, prevent or ameliorate an ailment or pathological condition, or treat a physical abnormality or deformity such as by physiotherapy or surgery.

Methods that involve performing surgery on the human or animal body are excluded, whether the effect of the surgery is therapeutic or not. Methods that involve the excision of tissue, organ, or tumour samples from the body are considered to be forms of surgery, and are excluded regardless of their reproducibility. The removal of fluids from the body such as by needle or cannula is not of itself surgery.

Methods for diagnosing disease are not methods of medical treatment, and are therefore not excluded as such.

A detailed consideration of "medical and surgical methods" can be found in section 17.02.03 of this manual.

12.05.03 Higher life forms

The Supreme Court determined in *Harvard College v. Canada (Commissioner of Patents)* that higher life forms are excluded from patentability by virtue of their not being either manufactures or compositions of matter within the meaning of the definition of "invention".[23] Fertilized eggs and totipotent stem cells (which have the inherent ability to develop into animals) are included in the higher life form proscription.

The Office similarly takes the position that organs and tissues are generally not to be viewed as being manufactures or compositions of matter.

A complete consideration of "higher life forms" and "organs and tissues" can be found in section 17.02.01 of this manual.

12.05.04 Forms of energy

Forms of energy, such as electromagnetic and acoustic signals, regions of the electromagnetic spectrum, electric currents, and explosions are considered not to be manufactured from or composed of matter in the sense intended by the *Patent Act*. A form of energy is consequently considered not to fall within any of the categories of subject-matter defined in section 2, and more particularly not to be a "composition of matter" or a "manufacture" within the definitions provided in 12.02.[24]

12.06 Guidance on certain subject-matter

The following sections provide additional guidance on assessing whether or not the matter of a claim is, in form and substance, a statutory invention.

Section 13.05.03 of this manual sets forth guidance on identifying what within a claim has been contributed by the inventors. To be patentable, the contribution must include a statutory practical form [see 12.03].

It is important to distinguish between the practical problem that is being addressed and the end use to which the invention may be put. It is not necessary that the purpose for which the invention will be used be statutory, as long as the claims define a statutory practical form of the invention and not simply its non-statutory purpose.

An art or process otherwise meeting the requirements for patentability is not made non-statutory simply because it does not produce a statutory product or effect. A diagnostic medical method, for example, may be statutory despite that it merely produces information (which is, of itself, non-statutory). Similarly, a method for printing books may be statutory, while the printed matter in the product books may well not be.

A machine, article of manufacture, or compositions of matter, similarly, is not excluded from patentability solely on the grounds that it is to be used in a non-technological field. [See 12.06.03]

The following sections are intended, in respect of certain subject-matter, to clarify the foregoing statements.

12.06.01 Features of solely intellectual or aesthetic significance

The expression "feature having a purely intellectual or aesthetic significance" applies to certain features that cannot, in a practical sense, affect the functioning of an invention. Such a feature therefore cannot change the manner in which the practical form of an invention operates to solve the problem for which it is the solution, and consequently can never be an essential element of a statutory invention.

Where a claim includes a feature having a solely intellectual or aesthetic significance, and no statutory feature of the claim appears to form part of the contribution, the claim is objected to under section 2 of the *Patent Act* on the grounds that the feature having solely intellectual or aesthetic significance is not, of itself, a statutory invention [see section 13.05.03*b* of this manual].[25]

Printed matter having purely intellectual significance, such as literary works, falls within this exclusion [See 12.06.04].

Where an invention requires a technical problem to be solved in order to enable a result or effect having a solely intellectual or aesthetic significance, the patentability of the invention is not diminished by the fact its purpose is to produce a non-statutory result or effect.[26]

12.06.02 Schemes, plans, rules, and mental processes

A scheme, plan or rule for performing an operation, achieving a result, controlling a method, or the like,[27] or a process that is exclusively a series of mental steps,[28] regardless of the reproducibility of these same (e.g. performing calculations; manipulating data or information to produce data or information having a different purely intellectual meaning or aesthetic significance), is disembodied (abstract) and is not a practical form of an invention.

All of the foregoing, consequently, are not by themselves "inventions" within the meaning of section 2 of the *Patent Act*. They are objectionable when claimed as such, or when present in a claim wherein the contribution does not include any statutory subject-matter.

In *Re Application No. 2,246,933 of Amazon.Com*, such a conclusion was reached and was expressed by reference to an exclusion from patentability of "business methods".[29] The term "business method" refers in such a context to a scheme or plan for conducting commercial interactions.

Where, however, a scheme, plan, rule or mental process serves to limit the technological nature of a statutory element in a claim, it is the so-limited statutory element that is a discrete feature of the claim [see section 13.05.03*a* of this manual].

A computer program (i.e. when not stored on a carrier), whether it takes the form of a proposed series of steps (e.g. a scheme or flow chart) or of specific code or pseudo-code, is effectively a scheme, plan or set of rules for operating a computer and is abstract in character [see section 16.04.03*a* of this manual].

The character or condition of a physical object (machine, manufacture or composition of matter) is not changed by an intent to use or operate said object according to a scheme, plan or rule.

12.06.03 Fine arts

A subset of those fields that are not "fields of technology" (not "manual and productive arts") are those referred to collectively as the "fine arts". In *Re Application No. 003,389 of N.V. Organon*, a "fine art" was described as being "that having intellectual meaning or aesthetic appeal alone".[30] The term is understood to include activities such as exercising, dancing, acting, writing, teaching, hair dressing, cosmetology, flower arranging, painting pictures and playing musical instruments. Generally, any product derived from a fine art will also be non-statutory.

Fine arts, and the products thereof, are not the "practical form" of any invention since they do not solve any problem in respect of practical affairs. Typically, the features that distinguish a product produced by a fine art will have purely intellectual or aesthetic significance [see 12.06.01]. Printed matter having purely intellectual significance, such as literary works, is an example of this.[31]

The exclusion from patentability of fine arts does not extend to inventive materials and instruments made use of in practising a fine art. For example, while an artistic method of painting a picture and the resultant picture are non-statutory, an inventive easel for holding a canvas would be patentable. Similarly, the paints, paint-brushes etc. used in conjunction with the art (but not "derived from" the art as the picture is) are all statutory subject-matter.

12.06.04 Printed matter

A very recognizable application of the principle set out in 12.06.01 is in respect of printed matter. Where printed matter does not provide a new functionality to the substrate on which it is printed, there has not been a statutory contribution.[32] For the printed matter and the substrate to be, together, a practical form of an invention, they must solve a practical problem related to the use of the printed matter in general, and not based on the solely intellectual or aesthetic content of the printed matter itself.

By way of example, each of the following has been affirmed by the Commissioner as being patentable: a textile material bearing markings to enable greater precision during a manufacturing procedure,[33] a newspaper layout in which white space is left to facilitate reading when the paper is folded, a layout of text on a series of pages to facilitate a bookbinding process, and a layout of text on a ticket which permits the ticket to be divided either horizontally or vertically while ensuring all information will appear on both halves.[34]

In each of the foregoing, the printed matter gave to the combination a new mechanical functionality. The actual content of the printed matter was not the basis of the invention. Where printed matter has only an intellectual or aesthetic significance, it may conveniently be referred to as "non-functional descriptive matter".

The term "printed matter" should, in this sense, not be restricted to traditional "ink-on-paper" printing. Any display of information wherein the sole contribution is in the information itself is not a statutory invention.

Examples:

1. An application describes a scratch-off lottery ticket wherein the scratchable areas are arranged in a maze-pattern and the user must scratch cells to determine if they can move their way to the end of the maze.

Claim:

> 1. A scratch-off lottery ticket comprising a pattern of a plurality of intersecting pathways that define a maze, said pathways divided into individual cells, each cell including an indicator of direction and each cell being covered by an opaque scratchable material, wherein if the indicators of direction define a path from a first cell of the maze to a final cell of the maze, the lottery ticket is a "winning ticket".

Analysis: Scratchable lottery tickets are known in the art, and the ticket defined in the claim is distinguished from other tickets on the basis of the maze pattern and the indicators of direction. The ticket provides no new and inventive mechanical function in respect of scratchable lottery tickets. Although the backing and the scratchable coating are, themselves, statutory subject-matter, they have not been contributed by the inventors. The only potential contribution is the maze pattern and the indicators of direction, which are printed matter having solely intellectual meaning and are not a statutory invention. Where a claim includes discrete statutory and non-statutory features, and the contribution does not include any of the statutory features, the claim is objected to for not defining a statutory "invention" within the meaning of section 2 of the *Patent Act* [see section 13.05.03*b* of this manual]. It is not necessary for the examiner to determine whether or not a discrete non-statutory feature is actually a contribution.

2. An application discloses the nuclear coordinates of a crystal of a molecule X, and a general purpose computer having stored thereon known molecular modelling software. The applicants are the first to isolate a crystal of molecule X and determine its nuclear coordinates using X-ray diffraction.

Claim:

> 1. A computer including a program means for displaying images of molecules, said computer containing stored data associated with the nuclear coordinates of molecule X and being capable of displaying an image of molecule X when said stored data is processed by said program means.

Analysis: The contribution lies in the nuclear coordinates of molecule X and the visual representation of the molecule. The computer is therefore distinguished from other computers only on the basis of data stored or displayed by it. The data does not solve a technological problem related to computers, and the computer and data are therefore discrete elements of the claim. The computer has not been contributed. The claim includes both a discrete statutory feature (the computer) and a discrete non-statutory feature (the data). Where it is determined that such a claim does not include any contributed statutory subject-matter, the claim is objected to for not defining a statutory "invention" within the meaning of section 2 of the *Patent Act* [see section 13.05.03*b* of this manual].

12.06.05 Games

A manner of playing a game or sport does not solve any practical problem in a field of technology, and a method for playing a game is consequently not statutory. This is so whether the claimed method is distinguished on the basis of specific rules governing play[35] or in terms of actions to be taken to achieve specific game-related results.

As noted in 12.06.03, however, this is not to say that tools made use of in the playing of a game may not themselves be patentable (e.g. a specially designed table or playing piece, a game board with a particular mechanical function, or combination of such that is patentable on its own merits).[36]

Despite that a tool for playing a game may be patented, a method of using that tool to play a game would nevertheless be non-statutory.

12.06.06 Computer-related inventions

Computers are widely recognized as general-purpose machines for performing logic functions and calculations, and for storing, manipulating and displaying data.

The term "computer" as used in this section refers to an electronic device comprising a central processing unit (CPU or "processor"). The term is commonly understood to mean a "general purpose computer", such as a desktop or laptop computer which is capable of receiving input, such as via a keyboard, and providing output, such as to a display means. The term can also be applied to network servers, personal digital assistants (PDAs), multi-function cell phones, etc., and applies to the device itself, generally understood as being the assemblage of elements contained within a single case or housing. In certain contexts, the term must be understood to include certain ubiquitous peripherals such as a keyboard, mouse or display necessary for interacting with the computer itself.

Computer-related inventions are typically claimed in the form of a method, device or computer program. Computer programs are covered in section 12.06.02, and the entire subject of computer-related inventions is covered in all its aspects in chapter 16 of this manual.

A guiding principle in respect of computer-related inventions was provided by the Federal Court of Appeal in *Schlumberger*, which noted that "the fact that a computer is or should be used to implement a discovery does not change the nature of that discovery", and also that the presence of a computer cannot effect the "transforming into patentable subject-matter [of] what would, otherwise, be clearly not patentable".[37]

12.06.06*a* Computer-related method claims

Many methods involve the use of a computer or an apparatus or system including a computer. Whether or not a method relying on a device is statutory is independent of the presence of the device.

A method that, on its own merits, would be considered non-statutory does not become statutory simply by virtue of some part of the method being carried out on or by a computer. The method itself, as a whole, must be a solution to a practical problem and must lie within a field of technology. [See 12.03 and 12.04]

12.06.06*b* Computer-related device claims

A device such as a computer itself or an apparatus or system including a computer associated with other devices is generally viewed as falling within the category of “machine”.

Whether or not a claim to a device is patentable depends on the presence of a contribution in the claim and the nature of this contribution [see section 13.05.03 of this manual]. As noted in section 13.05.03*b*, for a claim to be patentable it must define at least one statutory element that forms part of the contribution. For a claim to a device to be patentable, the device itself must therefore be a contributed practical form. That is, the device must provide a novel and unobvious technological solution to a technological problem.

Determining whether or not this is the case can be performed by assessing the device itself, but in many cases can also be performed indirectly by reference to the method implemented by the device. Where a statutory method is implemented by a computer, apparatus or system, a device capable of implementing the entire method is necessarily a solution to a practical problem. Presuming the device has been specifically modified to implement the method, such that the device is novel and unobvious, it will be a statutory contribution. Whether modifying the device is done by hardware or software is not important.

Nothing determinative arises, in respect of the patentability of a device, from the mere fact that the device implements a non-statutory method or is intended for use in a non-statutory method. To be patentable, the device must provide a novel and inventive technological solution to a technological problem.

Where a device does provide a technological solution to a technological problem, the manner by which the device is adapted to provide that solution is also not determinative. That is, the device could be adapted by providing new hardware or by controlling existing hardware in a particular manner by the addition of software or firmware (software programmed into a read-only memory).

Note that the “technological solution to a technological problem” does not have to be in relation to the operation of the computer as a general purpose device (e.g. it is not necessary that a computer be made more efficient or reliable), but could be simply that the general purpose device has been adapted to act as a special purpose device. Thus, presuming novelty and ingenuity, any of the following provide technological solutions to technological problems and would be viewed as contributed devices: a computer programmed to allow its speakers to provide “surround sound”, a computer adapted to operate using two central processing units, a computer programmed to allocate memory to video processing in a manner that increases the efficiency of the device when running several applications, and a computer whose motherboard has an inventive new video card slot with a faster data transfer rate.

Where a computer or other device does not provide a solution to a technological problem, the computer or device as a whole is not a contributed practical form of an invention. Where the device is further defined in terms of discrete non-statutory features, the claim would be objected to on the ground that it does not define a statutory "invention" within the meaning of section 2 of the *Patent Act* [see section 13.05.03*b* of this manual]. For example, a computer or other programmable device cannot be patentably distinguished from other computers on the basis of data stored on it. The reason for this parallels those given in 12.06.04; storing data on the computer does not make the computer a new and unobvious solution to a practical problem.

Example:

1. An application discloses a method for optimizing the performance of a cell phone network, by dynamic allocation of traffic and control channels. Channel assignments are calculated according to novel algorithm X programmed onto a general purpose computer, which outputs the channels to be allocated to a device that allocates the channels to the base stations. Consider that, in view of the prior art, the method and the network performing the method are determined to be novel, inventive and useful.

Claims:

1. A method for dynamically allocating control channels to base stations in a radiocommunication system comprising the steps of:
   - a associating a traffic channel with a control channel according to algorithm X;
   - b allocating the traffic channels to the base stations; and
   - c allocating the control channels to the base stations based on the allocation of traffic channels in b.

2. A radiocommunication system that allocates control channels to base stations according to the method of claim 1.

3. A radiocommunication system that operates on channels assigned according to the method of claim 1.

4. A computer for determining the assignment of traffic and control channels for the method of claim 1, said computer programmed to associate a traffic channel with a control channel according to algorithm X.

Analysis: Claim 1 defines a method that solves a technological problem relating to the operation of a cell phone network. The method includes the physical steps of assigning channels to the base stations, which alters their character or condition by imposing a technological limitation on their operating parameters (the channels they will use), and therefore is a statutory practical form. Novelty, ingenuity and utility being given, claim 1 is allowable.

Claim 2 is an apparatus or system (the cell phone network itself) in which traffic and control channels are assigned to its base stations according to algorithm X. The system implements the entire method of claim 1, and provides a novel and unobvious solution to a practical problem. The claim includes a statutory contribution (the novel system implementing the unobvious and useful method), and is patentable.

Claim 3 is a system that operates in an unspecified manner, but on the same channels as would be allocated using the method of claim 1. Since the system does not necessarily implement the inventive method of claim 1 in order to allocate channels, its patentability must be evaluated independently of the method. Although the system is statutory and presumably useful, it is not necessarily novel or unobvious. It would, for example, be anticipated by any radiocommunication system operating on a channel allocated by the method of claim 1.

Claim 4 defines a computer that implements only part of the method of claim 1. The computer, as a generic assemblage of hardware and software, differs from other computers only in having been programmed to perform the channel allocation required by the method of claim 1. Performing these calculations yields only information, and did not require any technological solution to a technological problem in the operation of the machine. The computer and the program to associate traffic and control channels are therefore discrete elements of the claim. The computer is a statutory feature, and the computer program (when considered in isolation) is a non-statutory feature. Where a claim includes discrete statutory and non-statutory features, and none of the statutory features has been contributed, the claim is objected to for not defining a statutory "invention" within the meaning of section 2 of the *Patent Act* [see section 13.05.03*b* of this manual].

12.06.07 Carrier substrates and storage media

As noted in 12.06.04, printed matter that does not provide new mechanical function to its display means does not transform the display means into an invention. Such printed matter itself is of purely intellectual or aesthetic significance and is not a statutory invention.

The principle can be reduced to the idea that using a known display means for its intended purpose of displaying information is not inventive, and cannot be viewed as being a contribution to the art of display means.

The principle applies equally to the storage of information using known storage means. A piece of music stored on a record, CD, DVD, or hard drive is not a solution to a technological problem, and using a storage means for its intended purpose is not a contribution. As the piece of music itself is a fine art [see 12.06.03], a claim to a piece of music stored on a known storage means does not contribute a statutory "invention" within the meaning of section 2 of the *Patent Act*.

As noted in 12.05.04, an acoustic, electric or electromagnetic signal is not statutory subject-matter. Claiming a signal in association with a carrier such as an electric wire or a fibre-optic cable does not introduce a statutory contribution where the carrier is simply being used for its known purpose of transmission.

As noted in 12.06.02, a computer program is not, of itself, statutory subject-matter. Where a computer program, in computer-executable form, is stored on a storage means (such as a hard drive, USB key, CD, DVD, etc.), the resulting product will be a statutory contribution if the program causes the device it controls to provide a technological solution to a technological problem.

12.06.08 New uses

A *use*, as noted in 12.02.01, falls within the category *art*. A *use*, like a *method* or a *process*, is a manner of achieving a result. In the case of a *use*, the result is achieved by the application of a particular means.

A *use* is distinguished from a *method* in that the latter involves directing the person skilled in the art to take a step or series of steps to arrive at the desired result. In contrast, a *use* must not require any specific step or steps to be followed. Rather, a *use* is defined only in terms of the means to be applied, the circumstances of this application, and the result to be achieved. The "how" of implementing a *use* must be left to the common general knowledge of the person skilled in the art. A claim that purports to be a *use* claim (e.g. a claim that begins "the use of") but that defines specific steps to be followed is, in effect, a method and must be examined as such.

From the foregoing, it can be appreciated that where, having been told the circumstances in which the *use* is to be practised, what means are to be used, and what result is to be achieved, the implementation is not known or obvious to the person skilled in the art, the *use* is not enabled. In such cases, the invention must be claimed in terms of the necessary steps to be taken to achieve the result and should (not "must"; see below) be claimed as a *method*. The steps are essential elements of the invention.

In many fields, however, the distinction between a *use* and a *method* is of no practical importance; where a specific *method* would be statutory, the corresponding *use* would also be statutory. Where an examiner is satisfied that the claim defines all the essential elements of the invention, if a claim beginning "the use of" also includes steps, and is in reality a method, there is nevertheless little likelihood of confusion as to the scope of the claim and the true nature of the invention being defined.

In fields where the distinction between a *use* and a *method* is important, this distinction must extend to both the form and substance of the claimed invention [see sections 13.05.02 and 13.05.03 of this manual]. On the form side, the requirement is simply that the *use* cannot be claimed in terms of any required steps. On the substance side, the analysis is best performed by identifying which features of the claim being examined distinguish the invention from the prior art. If these features all relate to the "how" of the use, the substance of the claim is a *method* and the contribution is not a *use*.[38]

Where the distinction between methods and uses is important is in fields where a *method* would be non-statutory but a related *use* would be statutory. This situation relates particularly to the pharmaceutical fields, where a method of treating a patient by some means is non-statutory but the use of a means in the treatment of a patient is statutory. Thus, a claim to "a method of treating a patient having disease Y, comprising administering to said patient drug X" is an excluded method of medical treatment, whereas the claim "the use of drug X to treat disease Y" would be considered statutory.

12.06.08*a* Uses of novel and inventive means

Where the means defined in a *use* claim is itself new and unobvious, it follows that any specific *use* of that means is contributed.

The claim must, of course, include all the elements necessary to achieve the promised utility (i.e. the essential elements of the invention) and must not, by its form, define excluded matter. That is, the *use* must be in a field of technology and the claim must not include active steps that render it a non-statutory method.

12.06.08*b* Uses to achieve non-analogous results

Where the means to be applied is known (i.e. lacks novelty), but is being used to achieve a result that is not analogous to a result it was known to be useful for (i.e. where it would not have been obvious at the claim date that the means would provide the promised result), a new *use* of that means has been contributed.

A "non-analogous" result arises in circumstances where the means would not usually have been applied, such as where the means is applied in a different field, or to achieve an otherwise entirely unrelated result. The use of a toxic chemical, previously used as a rat poison, as a growth promoter in plants would be a non-analogous use.

As always, it is necessary that the claim define all the essential elements of the invention and, by its form, not define excluded matter. If, for example, the toxic chemical in the previous paragraph would only work as a growth promoter in certain concentrations, this would need to be defined in the *use* claim. If a *use* claim defined that the plant whose growth was promoted had medicinal properties, and further included a step wherein the plant was administered to a sick animal, the claim would, by its form, be an excluded method of medical treatment.

12.06.08*c* Uses to achieve analogous results

Where a means is known to be useful to achieve a generic result in a given field, it may be discovered that it can be used to obtain a more specific result in that field. The term "analogous result" is used to mean such a selected or otherwise limited specific result.

Where a generic means was known to achieve a generic result, the selection of a specific means from the generic means might provide a substantial advantage. Where the means has already been made, it cannot itself be claimed. But as long as it was not previously used to achieve the specific result, its selection to achieve that result contributes a new *use*. Thus, if it was previously known to use non-steroidal anti-inflammatory drugs (NSAIDs; a generic means) to treat headache (a generic result), but subsequently discovered that one NSAID in particular (a specific means selected from the generic means) did not produce any gastrointestinal side-effects (a specific result), the use of that NSAID in particular to treat headache without side-effects would be an analogous result.

Where a specific means was known to achieve a generic result, but was later discovered to also achieve a specific result under selected circumstances, the resultant *use* claim must be carefully considered to ensure the selection of the specific circumstances is not a "how" limitation applied to the previously known use. If the only difference between the new use and the old analogous use lies in the specifics of "how" the old use is practised, the claim, in substance, is a *method*.

Consider that NSAID X (a specific means) was known to treat headache (a generic result), but it was later discovered and disclosed that by dosing the NSAID according to a specific schedule an improvement in the treatment of headaches (reduced gastrointestinal side effects) is achieved. The difference between the old use of NSAID X and the new one is "how" the drug is administered. A claim to "the use of NSAID X to treat headache with reduced gastrointestinal side effects" is, in substance, a new method of medical treatment. This is so whether or not specific method steps are defined, and regardless of whether they are defined in the active or passive voice. Thus, the following claims would all, in substance, be objectionable in the given circumstances:

1. The use of NSAID X to treat headache with reduced gastrointestinal side effects.
2. The use of NSAID X to treat headache with reduced gastrointestinal side effects, wherein the NSAID is administered three times daily.
3. The use of NSAID X to treat headache, wherein reduced gastrointestinal side effects are obtained when administration of the NSAID occurs three times daily.

Claim 1 adds to the known use an additional desired result that can only be achieved through the particular manner of administration. When understood in view of the description, the claimed invention would be understood to distinguish over the prior art only in respect of "how" the desired result is achieved. Claim 3, similarly, distinguishes over the prior art in terms of "how" the administration is performed. Although both claims 1 and 3 are in an acceptable form, they are both in substance methods of medical treatment. Claim 2 defines the same subject-matter as claim 3, but uses active language to define the administration. The presence of the active step of administration means that the claim is not, by its form, properly a use. It would be examined as a method, and rejected as a method of medical treatment.

12.06.08*d* Medical uses

As noted above, where a use relates to medicine the distinction between a *use* and a *method* is critical to the patentability of the claimed invention. Depending upon how a *use* claim is worded, it risks being, in form or substance, a *method* [see 12.06.08].

Generally speaking, any level of detail can be used in defining the nature of the means to be applied, as long as the details pertain specifically to the physical nature of the means itself. Thus, where the *use* involves a medicament, the medicament could be defined in terms of its physical state, form, composition, properties, concentration, or other physical characteristics relevant to the proper operation of the invention. Such features define the physical nature of the medicament as a composition of matter.

Similarly, the result to be achieved can be defined to whatever level of precision is necessary in the circumstances of the invention. In a medical *use*, the result is typically defined as "in the treatment of disease X" or similarly. Again, how narrowly X must be defined ("in the treatment of disease", "for treating autoimmune disorders", "in treating arthritis", "in the treatment of systemic lupus") will depend on the circumstances of the invention.

Where, in order to clear the prior art, it is necessary to limit a generic result to a specific result, it must be remembered that the person skilled in the art must be able to reproducibly achieve this result by applying ("using") the means according to their common general knowledge. If the specific result would not be reproducibly achieved when the means was used according to this knowledge, further "how" limitations are necessary to guide the person skilled in the art to inevitably succeed. The inclusion of these essential elements into the claim, however, will likely cause the claim to be, in substance, a *method*.

12.06.08*e* Uses of methods

Canadian jurisprudence appears to acknowledge that the means in a *use* claim can itself be a method.[39] The use of a method to achieve a different result is, in effect, a method. Using the *use* format is simply a shorthand for incorporating the physical steps of the method (the means), with the promised result of the *use* becoming the promised result of the *method*.

Thus, if "a method for filtering particulates from acidified wastewater, comprising the steps of [A, B, C]" is known as the "ABC filtration method", a claim to "the use of the ABC filtration method for filtering *E. coli* from drinking water" is a claim to "a method for filtering *E. coli* from drinking water, comprising the steps of [A, B, C]".

Note that the *use* of a method of medical treatment will, by consequence, always be considered non-statutory.

It is also worth noting that a claim to a *use* setting out the same result as the corresponding *method* is a redundant claim. Using the foregoing example, a claim to "the use of the ABC filtration method for filtering particulates from acidified wastewater" is conterminous with the *method* itself.

12.07 Office actions on subject-matter

A claim may be rejected as not defining a statutory invention for several reasons [see section 13.05.03*b* of this manual]. These are, principally:

1) if the claim does not define any statutory features;
2) if the claim, on its face, is directed to excluded subject-matter; and
3) if the claim includes both statutory and non-statutory discrete features, and it is determined that none of the statutory features was contributed.

Situations 1) and 2) correspond to the two alternatives included in case ii) in 13.05.03*b*, and point 3) corresponds to case iii).

Under situation 1), if the claim does not include a physical object or an art or process comprising at least one physical step [see 12.03], then the claim is rejected on the grounds that it does not include any statutory features.

Under situation 2), if any one embodiment encompassed by a claim is excluded subject-matter as described in 12.05 or 12.06, the claim is rejected for including non-statutory matter.

Under situation 3), the claim has been analysed as set out in 13.05.03*a* and found to include both statutory and non-statutory discrete features. If it is concluded that no statutory contribution exists, the claim is rejected for not defining a statutory "invention" within the meaning of section 2 of the *Patent Act*.

Under situation 3), the report should include the contribution analysis in a clearly identified section [see section 13.06 of this manual]. It is important that this analysis be clear and that it be presented separately from any objections resulting from the analysis itself. The contribution analysis is necessarily concerned with identifying what within a claim is new and inventive and, particularly where this determination is made in view of prior art, the analysis can resemble that used in evaluating novelty and/or inventive step. It is important that the objection to the absence of a statutory "invention" not resemble an objection to lack of novelty or to obviousness.

Where the practical form defined in the claim lacks novelty or inventive step, the appropriate objections are raised independently of and in addition to any objection to the claim under section 2.

12.08 Utility

Presuming that the claims define statutory subject-matter, section 2 of the *Patent Act* also requires that the matter of an invention be useful. Utility in the sense of the *Patent Act* can be considered as a requirement for an invention to be operable, controllable and reproducible.

The utility of an invention must be specific (a particular utility must be disclosed, rather than a generic indication that the invention may be "useful" in a given field),[40] practical (in the sense of addressing a need in a manual or productive art),[41] and credible (in the sense of being supported by the description in a manner sufficient for the person skilled in the art to expect it to be realizable and to be able to operate it to the same advantage as the inventors - see 12.08.06).

Utility is an essential aspect of an invention, but the utility of a physical object does not need to be explicitly defined in the claims.[42] (Since an art or process is always directed to a specific purpose, their utility will always be defined in each claim.) To be directed to a useful embodiment, a claim must define the inventive element or combination of elements necessary to enable the proper operation of the invention for its intended purposes.[43] A feature that is required to allow the invention to work, but which is not part of the invention *per se* (i.e. whose presence is understood by the person skilled in the art as being implicit) need not be defined.[44]

12.08.01 Operability

In simplest terms, the requirement that an invention be operable is simply an indication that it needs to work for its intended purpose.

The Supreme Court affirmed in *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* that, for the purposes of Canadian law, a lack of utility exists if "the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do"[45] and that "[i]f and when used in accordance with the directions contained in the specification, the promised results are obtained, the invention is useful in the sense in which that term is used in the patent law".[46] This was merely the reiteration of a long-accepted[47] and extant[48] standard.

Where the utility of an invention is self-evident to the person skilled in the art, and no particular promise has been made in regard to any advantages of the invention (e.g. if the invention was to simplify a known invention), the self-evident utility is sufficient to meet the required standard.

Where, however, the inventors promise that their invention will provide particular advantages (e.g. will do something better or more efficiently or will be useful for a previously unrecognized purpose) it is this utility that the invention must in fact have.

Although an invention need only have one use in order to be patentable, where several uses are promised the applicant must be in a position to establish each of them. For example, if a composition is promised to be useful as a drug, the applicant must be in a position to show that it is useful in the therapy of at least one disease. If, however, it is promised to be useful as a drug for treating many diseases, the applicant must be in a position to establish its utility [see 12.08.03 & 12.08.05] in treating each of the diseases.

12.08.02 Controllability and reproducibility

Further, to be considered to have utility an invention must be controllable and reproducible.[49] This means that the desired result must inevitably follow when the invention is put into practice. It is to be noted that the idea that the "desired result must inevitably follow" can refer to an accepted degree of success of a particular repetitive mass production method. For example, if a method is known and universally recognized in a particular art of having a success rate under a certain ratio or percentage of rejects, the desired result inevitably follows if this method is inside such parameters.

Inventions that are arrived at by chance, and which cannot be reliably reproduced, lack utility.[50] An invention that relies on the judgement or reasoning of an operator is deemed to lack reproducibility and consequently to lack utility.[51]

Certain mental steps involving the ascertaining and sensing facilities have precise and predictable results, and do not of themselves cause the art or process that relies on them to lack utility. Whenever a person is called on to perform a subjective interpretation, however, the result will be subject to such factors as intuition, creativity, conjecture, and approximation and the result will not be objectively controllable or reproducible. This lack of control and reproducibility is amplified if the subjective judgement calls into play a person's system of values, beliefs, interests or preferences.

12.08.03 Establishing utility

The Supreme Court noted in *Apotex Inc. v. Wellcome Foundation Ltd.* (*Apotex* hereafter) that

> Utility is an essential part of the definition of an invention (*Patent Act*, s. 2). A policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove *invalidity*, without the patent owner's ever being put in a position to establish validity. Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner "by law" is required to refuse the patent (*Patent Act*, s. 40).[52]

The utility to which the court is referring, of course, is that promised by the inventors (see 12.08.02).

Demonstrated utility pertains to embodiments of the invention that have been shown to actually work for the ends promised by the inventors. Utility can be demonstrated, for example, by the provision of working examples.

Soundly predicted utility pertains to embodiments of the invention which have not themselves been demonstrated to work for the ends promised by the inventors, but for which an appropriate basis exists upon which this utility can be predicted.

12.08.04 Sound prediction

In order for a prediction to be deemed to be "sound", it must meet the test set out in *Apotex*, namely that there must be:

(i) a factual basis for the prediction;
(ii) an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and
(iii) proper disclosure.

It is important to keep in mind that a "sound prediction" does not imply certainty. It is clear from the very term "prediction" that this is so. At the same time, the Supreme Court was clear in *Apotex* that a patent monopoly is not to be granted in return for mere speculation. Consequently, in assessing whether or not utility has been established via sound prediction the emphasis is appropriately placed on "sound", and the question is whether a prediction is "sound" or "speculative". In *Monsanto Co. v. Commissioner of Patents* (*Monsanto* hereafter), Pigeon J. adopted the following terms to express this lack of certainty: "[i]f it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so. Of course, in so doing he takes the risk that a defendant may be able to show that his prediction is unsound or that some bodies falling within the words he has used have no utility or [...] that some promise he has made in his specification is false in a material respect".[53]

It bears mentioning that the doctrine of sound prediction is of general applicability in every field for which patent protection may be sought.

12.08.04*a* Factual basis

Evaluating what will be a sufficient factual basis for a sound prediction must be conducted on a case-by-case basis, and will depend on such factors as:

(i) the scope of the claims;

(ii) the state of the art;

(iii) the nature of the invention and its predictability; and

(iv) the extent to which the applicant has explored the area claimed, for example by conducting experiments which provide factual support for the utility asserted.

It is clear from *Apotex* that, while the factual basis may be provided by way of examples, there is no absolute requirement that this be so. Depending on the circumstances, it is possible that the factual basis need not even be provided in the application. For example, the factual basis could be found in scientifically accepted laws or principles, in data forming part of the state of the art and which is referred to in the description, or in information forming part of the common general knowledge of the person skilled in the art.

12.08.04*b* Sound line of reasoning

In order to take a prediction from the realm of speculation and render it "sound", the applicant must be able to provide to the person skilled in the art an explanation of how it is that, on the basis of whatever facts have been identified, of the state of the art, and of whatever the inventors have brought to light in their researches, the entire matter of the claimed invention can be expected to provide the promised utility. Since a sound line of reasoning is directed to a person skilled in the art, those elements of the sound line of reasoning that would be self-evident to the person skilled in the art in view of their common general knowledge do not need to be explicitly disclosed in the application.

Although no inventor is required to understand why their invention works, this does not dilute the requirements for a sound prediction. If an inventor cannot articulate a line of reasoning to soundly connect their factual support (e.g. their examples) to the remaining matter of their claims, they are not entitled to the full breadth of their claims.

It is not possible to provide exhaustive guidance on the types of reasoning which may be found to be "sound". In brief, however, the soundness of a line of reasoning can be effectively assessed by asking whether the person skilled in the art (represented during examination by the examiner) would accept the logic presented in the line of reasoning and derive from the sound prediction as a whole an expectation that the invention will provide the promised utility.

12.08.04*c* Proper disclosure

The requirement for proper disclosure means that the person skilled in the art has to, through the specification alone, be provided with sufficient information to understand the basis of the sound prediction and to practice the entire scope of the claimed invention. Elements of either the factual basis or the sound line of reasoning that form part of the common general knowledge will not, as a general rule, need to be disclosed. Elements that form part of the state of the art could (depending on the specific circumstances) be properly disclosed merely by referring to the document in which they are contained. Elements known only to the inventors, however, need to be included in the description itself.

12.08.05 Relevant date

The applicant must be in a position to establish the utility of their invention no later than at their filing date. Consequently, the factual basis upon which either the demonstration or sound prediction are based must necessarily exist as of the filing date. Similarly, if a sound prediction is to be relied upon, the articulable and sound line of reasoning referred to in 12.08.04 must also exist as of the filing date. As put by Binnie J. in *Apotex*, "[n]or, in my view, is it enough for a patent owner to be able to buttress speculation with post-patent proof, and thereby to turn dross into gold".[54]

Where an applicant is claiming priority, this claim is valid only insofar as the document or documents upon which it is based are sufficient to establish the utility of the invention. Although an applicant is entitled to add matter not included in the priority document(s) to the application as filed, where this matter is necessary to establish the utility of any embodiments of the invention those embodiments do not benefit from the priority date.

12.08.06 Sufficiency of the description

As is apparent from the foregoing discussion, the question of utility is strongly associated with the question of proper disclosure (i.e. sufficiency of description). As the Supreme Court noted in *Apotex*, "[d]isclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*".[55]

Subsection 27(3) of the *Patent Act* requires (*inter alia*) that the description "correctly and fully describe the invention and its operation or use as contemplated by the inventor". Thorson P. summarized the requirements for sufficient specification in *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*,[56] and later described this "onus of disclosure" as "a heavy and exacting one".[57]

> The description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and must be as simple and distinct as the difficulty of description permits. It must not contain erroneous or misleading statements calculated to deceive or mislead the persons to whom the specification is addressed and render it difficult for them without trial and experiment to comprehend in what manner the invention is to be performed. It must not, for example, direct the use of alternative methods of putting it into effect if only one is practicable, even if persons skilled in the art would be likely to choose the practicable method. The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed.[58]

As was noted in section 12.08.04*c*, the description must contain sufficient information to support a sound prediction of the utility of the invention. Further, it must set out the invention such that a person skilled in the art can practice it having reference only to the description itself and to common general knowledge.

In *Consolboard*, Dickson J. accepted that "the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired".[59] The description must be able to answer the questions "What is your invention?: How does it work?"[60] such that "when the period of the monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application".[61]

A description sufficient to allow the public (in the form of a person skilled in the art) to practice the invention with the same success as the inventor is said to be enabling. Since the person skilled in the art is the addressee of the description, it is not necessary for common knowledge to be comprehensively disclosed nor to teach to the person skilled in the art things that would be plainly obvious to them.[62]

It is important to bear in mind that the specification must be sufficient to allow the full scope of the claimed invention to be practised without the need for the person skilled in the art to exercise their inventive ingenuity. If the person skilled in the art is called on to solve problems in such a manner that an inventive step would be present, the description is insufficient (and the attendant claims are unsupported).[63] The obligation of the patentee for proper disclosure in this sense was described in *Rice v. Christiani & Nielsen* as:

> [h]e must so draft his specification, that a person having a competent knowledge of the industry concerned [...] will be able readily to ascertain from it the relation the invention bears to the existing knowledge in the industry, and so that one should not be called upon to do experimental work in order to discover how the invention may be made operative. There must be an open exposition by the patentee of everything that is necessary for the easy and certain procurement of the commodity for which the patent was granted. The patentee is not to tell a man to make an experiment but to tell him how to do the thing.[64]

12.09 Office actions on utility

Where an examiner has reason to believe that an applicant is not in a position to establish the utility of their invention, where the manner whereby they have attempted to establish utility is defective or where there is evidence of inutility an objection will be raised. The nature of the objection will depend on the specific defect, and should serve to communicate the severity of the perceived deficiency.

If the perceived defect in a claim is one of scope (e.g. the invention has been claimed more broadly than the description appears to support, such that the entire claimed matter does not appear to have the promised utility), an objection can be presented under section 84 of the *Patent Rules* on the grounds of a lack of full support.

Such an objection could be made, for example, because an element of the invention (an "essential" element) has not been defined in the claim.

Similarly, when it does not appear that a sound prediction exists upon which the utility of the entire scope of the claim can be predicated, such that the scope of the claim consequently does not appear to be "fully supported" by the description, a rule 84 objection is appropriate.

Objections under section 84 of the *Patent Rules* suggest that the examiner views the defect in the claim as one of scope, and that it is remediable through amendment. If an applicant declines to amend, however, they are effectively asserting that the entire scope of the claim is their invention and objections to lack of utility (under section 2 of the *Patent Act*) and lack of sufficiency of disclosure (under subsection 27(3) of the *Patent Act*) could be raised in a subsequent report.

Section 2 of the *Patent Act* requires that an invention be useful. When an examiner has reason to believe that the invention as claimed lacks utility, and the matter is not of the nature described above in relation to section 84 of the *Patent Rules*, an objection is raised under section 2 of the *Patent Act*.

In *Monsanto v. Commissioner of Patents*, it was noted that inutility should only be alleged on the basis of evidence of inutility or of a reasoned argument as to why the applicant's sound prediction of utility is defective.[65] An objection contending an applicant's sound prediction is flawed should be supported by setting out sufficient facts and reasoning to rebut the applicant's contention. The applicant must be given a sufficiently clear argument by the examiner that they are able to respond in an informed manner to those concerns raised by the examiner.

If the perceived defect is that the specification is, in view of the criteria set out in *Apotex*, insufficient to support a sound prediction, this should be clearly communicated. Where the defect is of the nature that no factual basis appears to exist or that no line of reasoning appears to exist (whether by explicit disclosure or in view of the common general knowledge of the person skilled in the art), the "reasoned argument" can be simply identifying these apparent omissions. In such cases, the objection to the claims under section 2 of the *Patent Act* should be accompanied by an objection to the description under subsection 27(3) of the *Patent Act*.

Conversely, even when an applicant has demonstrated and/or soundly predicted the utility of their invention, it may be the case that some basis exists (a factual basis such as data in the prior art, contravention of a law of science etc.) to contend inutility in regard to some embodiment of the invention. When such a basis can be identified, even as regards only one embodiment of a broad claim, the claim is objected to on the grounds of a lack of utility.

It should be noted that evidence of inutility can be provided at any time. There is no requirement that such evidence have existed as of the application's claim date.

On occasion, an examiner may be presented with an alleged invention that is contrary to known scientific principles. Unless the proper operation of such an invention can be established by demonstration, the claims defining it are rejected for lack of utility and the description for lack of proper disclosure.[66] Depending on the nature of the invention, it may be helpful to request the provision of a working model of the invention in accordance with section 38 of the *Patent Act*.

Example:

1. An application discloses a golf club having on the face of the club a pattern of features which are said to improve the trajectory of a ball struck by the club.

Claim:

1. A golf club having a striking surface adapted with a design comprising [details of design].

Analysis: the question of whether or not the club is patentable is related to whether or not it provides the promised utility of improving the trajectory of a ball struck by the club. If no basis is provided in the application to conclude that the promised utility was established by demonstration, it must be presumed that the applicant intends to establish utility by sound prediction. In this case, a correct explanation by the inventor of why the design will controllably and reproducibly lead to an improved trajectory would be necessary to support the claim. If the applicant could not establish the utility of the design in improving the club, the claim would be rejected for being distinguished over the prior art only by an aesthetic feature. [See 12.06.01]

Endnotes for Chapter 12

1. *Apotex Inc. v. Wellcome Foundation Ltd.* [2002] SCC 77 [(2002), 21 C.P.R. (4th), 499 (S.C.C.)] at paragraph 37

2. *Biolyse Pharma Corporation v. Bristol-Myers Squibb Company* [2005] SCC 26 at paragraph 1

3. *Shell Oil v. Commissioner of Patents* [(1982), 67 C.P.R. (2nd), 1 (S.C.C.)] at pages 10-11

4. *Canadian Gypsum Co. Ltd. v. Gypsum, Lime & Alabastine, Canada, Ltd.* [1931] Ex.C.R. 180

5. *Tennessee Eastman v. Commissioner of Patents* [(1972), 8 C.P.R. (2nd), 202 (S.C.C.)]

6. *Shell* (supra at 3) at pages 10-11.

7. *Lawson v. Commissioner of Patents* [(1970), 62 C.P.R. (1st), 101 (Ex.Ct.)] at page 109; this definition of "method" was referred with approbation in *Shell Oil* (supra at 3) at page 15.

8. Physical is used here in the senses of "relating to things perceived through the senses as opposed to the mind; tangible or concrete" and "relating to physics or the operation of natural forces generally". ["Physical *adjective*", *The Oxford Dictionary of English (revised edition)*, Oxford University Press 2005.] For greater clarity, it is noted that where a chemical art or process is being considered, the terms physical agent and physical object include compositions of matter and the change in character or condition may be physical or chemical in nature.

9. *Commissioner of Patents v. Ciba Ltd.* [(1959), 30 C.P.R. (1st), 135 (S.C.C.)] at page 141; aff'g [(1957), 27 C.P.R. (1st), 82 (Ex.Ct.)]

10. "machine *noun*" *The Oxford Dictionary of English (revised edition)*, Oxford University Press 2005; "machine" *The Concise Oxford Dictionary of Mathematics*, Oxford University Press 2005

11. *Harvard College v. Canada (Commissioner of Patents)* [2002] S.C.C. 76; [(2002), 21 C.P.R. (4th), 417 (S.C.C.)] at paragraph 159. The court relied on the definitions of the term in the *Oxford English Dictionary* and the *Grand Robert de la langue française*.

12. *Harvard* (supra at 11) at paragraphs 157-163

13. *Shell Oil* (supra at 3) at page 14

14. *Riello Canada, Inc. v. Lambert* [(1986), 9 C.P.R. (3rd), 324 (F.C.T.D.)] citing at pages 335 and 336 *Reynolds v. Herbert Smith & Co., Ltd.* [(1902), 20 R.P.C., 123 (Ch.D.)]

15. Technology is defined as "the application of scientific knowledge for practical purposes, especially in industry", "machinery and equipment developed from scientific knowledge", and "the branch of knowledge dealing with engineering or applied sciences". ["Technology *noun*", *The Oxford Dictionary of English (revised edition)*, Oxford University Press 2005.]

16. *Re Application No. 2,246,933 of Amazon.Com* (2009) C.D. 1290 at paragraphs 140-149

17. *Commissioner of Patents v. Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning* [(1963), 41 C.P.R. (1st), 9 (S.C.C.)] at page 17

18. *Harvard* (supra at 11) at paragraph 158

19. *Monsanto Canada Inc. v. Schmeiser* [2004] S.C.C. 34; [(2004), 31 C.P.R. (4th), 161 (S.C.C.)] at paragraph 132, in Arbour J.'s dissension in part.

20. *Schlumberger Canada Ltd. v. Commissioner of Patents* [(1981), 56 C.P.R. (2nd), 204 (F.C.A.)] at page 206

21. *Monsanto* (supra at 19) at paragraph 133.

22. *Tennessee Eastman* (supra at 5); *Imperial Chemical Industries Ltd. v. Commissioner of Patents* [(1986), 9 C.P.R. (3rd), 289 (F.C.A.)]

23. *Harvard College v. Canada (Commissioner of Patents)* [2002] S.C.C. 76; [(2002), 21 C.P.R. (4th), 417 (S.C.C.)]

24. *Office Practice Regarding Signals* C.P.O.R. Vol. 135, No. 33, August 14, 2007. The notice, strictly speaking, was limited in scope to electromagnetic and acoustic signals, but the reasoning applies equally to other forms of energy *per se*. Many observers point to the equation $E = mc^2$ as "proof" that any form of energy by necessity has mass (i.e. contains matter; is a material product), and that electromagnetic signals (for example) should therefore be patentable. It is noted in this context that the theory of general relativity leads to the conclusion that the mass of any object moving at the speed of light is infinite.

25. *Re Application No. 44,282 of Luebs* (1971) C.D. 80 (relating to wood panels wherein the novelty lay in particular inscribed designs); *Re Application No. ---995*

for a Townhouse Building Design [(1979) C.D. 605, 53 C.P.R. (2nd), 211 (P.A.B.)] (relating to architectural plans or designs); *Re Application 040,799 of Cowan* (1971) C.D. 79

26. *Re: Pilot Ink Co. Patent Application No. 565,417* [(1997) C.D. 1224, 86 C.P.R. (3rd), 66 (P.A.B.)]

27. *Lawson* (supra at 7) at page 115, in respect of "plans".

28. *Schlumberger* (supra at 20) at page 206

29. *Re Application No. 2,246,933 of Amazon.Com* (supra at 16)

30. *Re Application No. 003,389 of N.V. Organon* [(1973) C.D. 144, 15 C.P.R. (2nd), 253 (P.A.B.)]

31. *Re Application No. 996,098 of Boussac* (1973) C.D. 143

32. *Re Dixon Application No. 159,203* [(1978) C.D. 493, 60 C.P.R. (2nd), 105 (P.A.B.)], concluding that a sequence of words on a page, to improve the voice through exercise of the diaphragm, did not of themselves "serve any mechanical purpose" and were by consequence not statutory.

33. *Re Application of Boussac* (supra at 31)

34. In *Re Dixon* (supra at 32), the Commissioner cited with approval the conclusions reached in the UK cases *Cooper's Application* [(1902) 19 R.P.C. 53], *Fishburn's Application* [(1940) 57 R.P.C. 245]

35. *Re Application of Cowan* (supra at 25) - "It is well established that rules of play may not be used to substantiate invention".

36. *Re Application 055,210 of Boileau* (1971) C.D. 93

37. *Schlumberger* (supra at 20) at page 206

38. It is noted that this is, in fact, the reverse of the usual approach, which is to ask if a statutory contribution has been made. In the case of a use, it is not always easy to disentangle the part of the claim that is the *use* from the part that is a *method*. Where, however, it is known that the *method* aspects of the claim are non-statutory, a conclusion that only a method has been contributed by necessity means that a *use* has not been. It follows that the claim is, in substance, a *method*, and therefore (*ex hypothesi*) non-statutory.

39. *Calgon Carbon Corporation v. North Bay (City)* [2005] FCA 410 e.g. at paragraph 18

40. *Re Application of Abitibi Co.* [(1982) C.D. 933, 62 C.P.R. (2nd), 81 (P.A.B.)] at page 91 - an invention must serve to carry out some useful known objective and "cannot be a mere laboratory curiosity whose only claim to utility is as a starting material for further research".

41. *Re Application of Organon* (supra at 30) at page 258

42. *Eli Lilly & Co. v. Marzone Chemicals Ltd.* [(1977), 37 C.P.R. (2nd), 3 (F.C.T.D.)] at page 31, aff'd [(1978), 37 C.P.R. (2nd), 37 (F.C.A.)]

43. *Feherguard Products Ltd. v. Rocky's of BC Leisure Ltd.* [(1995), 60 C.P.R. (3rd), 512 (F.C.A.)] at pages 516 to 517

44. *Metalliflex Ltd. v. Rodi & Wienenberger AG* [1961] SCR 117 & [(1960), 35 C.P.R. (1st), 49 (S.C.C.)] at pages 53-54

45. *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at page 160 citing 29 Halsbury, 3rd ed., page 59

46. *Consolboard* (supra at 45) at page 161, citing *Unifloc Reagents Ltd. v Newstead Colliery Ltd.* [(1943), 60 R.P.C., 165]

47. *Northern Electric Co. v. Brown's Theaters Ltd.* [1940] Ex.C.R. 36 at paragraph 53 [(1940), 1 C.P.R. (1st), 180 (Ex. Ct.)], aff'd [1941] S.C.R. 224; *Wandscheer et al. v. Sicard Limitée* [(1944), 4 C.P.R. (1st), 5 (Ex.Ct.)] at page 15-16, aff'd [(1947), 8 C.P.R. (1st), 35 (S.C.C.)]

48. *Feherguard* (supra at 43) referring to *Consolboard* (supra at 45) at p. 518

49. *Re Application of Organon* (supra at 30) at page 258; the criteria "controllable and reproducible by the means disclosed" were commented on by the Federal Court of Appeal in *Harvard College v. Canada (Commissioner of Patents)* [(2000), 7 C.P.R. (4th), 1 (F.C.A.)] at paragraph 70 (page 26); it was clarified at paragraph 75 that these requirements pertain only to those features necessary to achieve the objects of the invention.

50. *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)* [(1989), 25 C.P.R. (3rd), 257 (S.C.C.)] at page 270

51. *Re Application for Patent Containing Claims that Read on Mental Steps* [(1972) C.D. xxx, 23 C.P.R. (2nd), 93] ; *Re Application 269,230 of Itek Corporation* (1981) C.D. 896

52. *Apotex Inc. v. Wellcome Foundation Ltd.* [2002] SCC 77 [(2002), 21 C.P.R. (4th), 499 (S.C.C.)] at paragraph 46

53. *Monsanto Co. v. Commissioner of Patents* [(1979), 42 C.P.R. (2nd), 161 (S.C.C.)] at page 176, citing *Olin Mathieson Chemical Corp. et al. v. Biorex Laboratories Ltd. et al.* [1970] R.P.C. 157

54. *Apotex* (supra at 52) at paragraph 46

55. *Apotex* (supra at 52) at paragraph 37

56. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)]

57. *Radio Corporation of America v. Raytheon Manufacturing Co.* [(1957), 27 C.P.R. (1st), 1 (Ex.Ct.)] at page 14

58. *Minerals Separation* (supra at 56) at page 111, with these points being reasserted by Thurlow J. in *Société des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd. et al.* [(1968), 55 C.P.R. (1st), 207 (S.C.C.)] at pages 225-226; *Wandscheer et al. v. Sicard Limitée* [(1947), 8 C.P.R. (1st), 35 (S.C.C.)] at pages 39-40.

59. *Consolboard* (supra at 45) at pages 154 to 155, Dickson J. quoting H.G. Fox from his *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.]

60. *Consolboard* (supra at 45) at page 157

61. *Minerals Separation* (supra at 56) at page 111

62. *Burton Parsons Chemical Inc. v. Hewlett-Packard (Canada) Ltd.* [(1976), 17 C.P.R. (2nd), 97 (S.C.C.)]

63. *Procter & Gamble Co. v. Bristol-Myers Canada Ltd.* [(1978), 39 C.P.R. (2nd), 145 (F.C.T.D.)] at pages 159-160, aff'd [(1979), 42 C.P.R. (2nd), 33 (F.C.A.)]

64. *Rice v. Christiani & Nielsen* [1929] Ex.C.R. 111 at paragraph 9 rev'd on other grounds

65. *Monsanto Co. v. Commissioner of Patents* [(1979), 42 C.P.R. (2nd), 161 (S.C.C.)]

66. *Re Application 213,113 of X* (1978) C.D. 509; *Re Application 312,909 of Cruikshank* (1980) C.D. 703; *Re Application 474,156 of Niderost* (1990) C.D. 1159; *Re: Application 2,145,007 of Meszaros* (2003) C.D. 1256

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Chapter 13
Examination of Applications

13.01 Scope of this chapter

The present chapter provides an overview of the examination of applications. The chapter discusses examination in terms of both the analysis of applications by a patent examiner and the procedural steps specifically related to examination that may apply to an application.

The chapter does not cover purely operational procedures such as the payment of maintenance fees.

The chapter introduces topics in roughly the order they would usually be encountered in the prosecution of an application, from the step of requesting examination through to completion of prosecution before an examiner.

The purpose of examination is to ensure that the specification, abstract and any drawings of an application comply with the formal and substantive requirements of the *Patent Act* and *Patent Rules*. Many of these requirements are discussed in detail in other chapters of this manual, and the present chapter will focus on certain aspects of examination not covered elsewhere.

13.02 Request for examination

Under the current *Patent Act*, applications are not examined automatically. Rather, Canada operates on a system of deferred examination, wherein an application is only examined upon request.

In accordance with subsection 35(1) of the *Patent Act*, a request for examination may be made by any person, as long as it is in the prescribed manner and accompanied by the necessary fee (set out in item 3 of Schedule II). The Commissioner of Patents may also, under subsection 35(2) of the *Patent Act*, require an applicant to request examination of their application.

If a request for examination is made by a third party, the Office will inform the applicant of this fact.

Section 95 of the *Patent Rules* sets out the information that must be included with a request for examination, this being:

(*a*) *the name and address of the person making the request;*
(*b*) *if the person making the request is not the applicant, the name of the applicant;*
(*c*) *information, such as the application number, sufficient to identify the application.*

Section 96 of the *Patent Rules* establishes that the request for examination must be made before the expiry of the five-year period after the filing date of the application or, in the case of a divisional application, the later of this five-year period and the six-month period after the date on which the divisional application is actually filed.

If a request for examination is not made within the prescribed period or within the time specified in a notice sent under subsection 35(2) of the *Patent Act*, the application will be considered abandoned in accordance with paragraph 73(1)(*d*) or 73(1)(*e*) of the *Patent Act*, respectively [see also section 20.02.07 of this manual].

13.03 Request to advance examination (special order)

Applications, including divisional applications, are generally examined sequentially according to the date on which their request for examination was made.[1]

Under subsection 28(1) of the *Patent Rules*, the Commissioner of Patents may advance an application for examination out of its routine order on the request of any person who pays the fee set out in item 4 of Schedule II, where the Commissioner determines that failure to advance the application is likely to prejudice that person's rights. Applications that are subject to advanced examination are commonly referred to as "special order" applications.

In accordance with subsection 28(2) of the *Patent Rules*, such a request can be made only if the application in question is open to public inspection under section 10 of the *Patent Act* and a request for examination has been made pursuant to subsection 35(1) of the *Patent Act*.

Although a third party may request that an application be examined, only the applicant may request that their application be laid open before the prescribed time. A third party may, therefore, only request advanced examination on a laid-open application. Where advanced examination is accorded at the request of a third party, the Office will inform the applicant of this by letter.

A request to advance examination will not be considered if the application in respect of which the request was made is incomplete [see Chapter 5 for completion requirements].

Once an application is given special order status, this status will generally apply for the duration of prosecution. The person who requested special order status can request that advanced examination cease, in which case the application will be examined in its regular order. The fee for requesting advanced examination is not refundable under section 4 of the *Patent Rules.*

13.04 Rule 29 requisitions

Section 29 of the *Patent Rules* provides that where an examiner has reasonable grounds to believe than an application for a patent describing the same invention has been filed, in or for any country, on behalf of the applicant or of any other person claiming under an inventor named in the application being examined, the examiner may requisition from the applicant any of the following information and a copy of any related document:

(*a*) an identification of any prior art cited in respect of the applications;
(*b*) the application numbers, filing dates and, if granted, the patent numbers;
(*c*) particulars of conflict, opposition, re-examination or similar proceedings; and
(*d*) translations into English or French of all or part of a relevant document not in one of those languages.

An applicant must respond to such a requisition by providing the information requested or by specifically stating that the information is not available to them, and why this is. This latter statement, required under subsection 29(3) of the *Patent Rules*, must be provided even where the reason certain information is unavailable is that it does not exist. The position of the Office is that a translation is generally available to the applicant if the document to be translated is available to them.

When a request for examination is made, an Office letter is sent to the applicant to confirm the request for examination and to ask the applicant to consider voluntarily submitting the information referred to in section 29 of the *Patent Rules* as it becomes available to them. Voluntary submission of this information reduces the likelihood that an examiner will need to make a formal requisition to obtain it. Applicants should generally not submit information which is readily available to the examiner (see below). The object of the voluntary submission of prior art is to expedite prosecution by bringing the attention of the examiner to documents that might otherwise not be immediately identified at the outset of examination. Where a document is identified to the Office, the applicant should generally not submit a copy of the document unless they have reason to believe that copies of that document will not be readily available to the examiner.

Examiners should not requisition an identification of prior art cited in published search reports to which the examiner has ready access. Such search reports include the International Search Report, and any European Patent Office or United States Patent and Trademark Office search reports available through the respective web sites of those Offices. Similarly, examiners should not requisition any information that is available to them through the web sites of those Offices, including particulars of examination, opposition, or similar proceedings.

Recognising that translating documents may place a significant financial burden on the applicant, requisitions for translations should be limited to cases where no viable alternative exists.

Where a foreign language document appears relevant to examination, an examiner should attempt to locate a version of that document (or minimally of its abstract) in an Official language with which they can work. In this regard, examiners should make use of reliable online translation engines, such as that provided by the JPO, at least at the early stages of examination.

Where an examiner is working from a machine translation or from a family member of a citable document, this should be clearly stated in the report. An applicant wishing to rebut arguments made on the basis of such a document, however, may be required to provide a translation of the document to support their arguments.

Where a translation is requisitioned, the applicant must provide, in accordance with paragraph 29(1)(*d*) of the *Patent Rules*, a translation of the document, or a part of the document, into English or French. Where only a part of the document is necessary for examination, an examiner should indicate, wherever possible, in respect of which part or parts of the document the requisition for a translation is being made.

Under Article 42 of the Patent Cooperation Treaty (PCT), no national office having received an international preliminary examination report (IPER) "may require that the applicant furnish copies, or information on the contents, of any papers connected with the examination relating to the same international application in any other elected Office". The Office considers Article 42 of the PCT to apply in respect of any application that has been the subject of International Preliminary Examination under Chapter II of the PCT.

The Office considers a requisition for the identification of prior art under paragraph 29(1)(*a*) of the *Patent Rules* or for application numbers, filing dates, and/or patent numbers under paragraph 29(1)(*b*) of the *Patent Rules* to comply with the requirements of Article 42 of the PCT. The information being requisitioned is connected with the search of the prior art, and is not considered to be a request for copies of papers, or information on the contents of papers, connected with examination. The Office also does not consider that conflict, opposition, re-examination and similar proceedings are "connected with examination" in the sense intended by Article 42 of the PCT, and consequently takes the position that requisitions under section 29 of the *Patent Rules* are consistent with Article 42 of the PCT.

13.05 Examination

Examiners and applicants interact primarily through written correspondence, which may take the form of voluntary amendments made by the applicant before or during examination, and of any examiners' reports and applicants' responses thereto which may arise in respect of an application.

These reports are, except in the case of a Final Action [see 13.08], issued under authority of subsection 30(2) of the *Patent Rules* which provides that:

> *Where an examiner [...] has reasonable grounds to believe that an application does not comply with the Act or these Rules, the examiner shall inform the applicant of the application's defects and shall requisition the applicant to amend the application in order to comply or to provide arguments as to why the application does comply...*

The content of a report is dealt with in section 13.06, and the remainder of this section addresses the analysis of an application performed by an examiner.

The purpose of examination is, at each stage, to perform a thorough analysis of the application to ensure it complies with the requirements of the *Patent Act* and *Patent Rules.* Particular guidance regarding specific requirements for obtaining a patent are set out in other chapters of this manual.

After having performed this analysis, the examiner must decide whether the application is allowable or a report must be issued. Where a report is to be issued, it should be as comprehensive as possible, to enable the applicant to make informed decisions regarding the continued prosecution of their application and, if possible, to place the application in a condition for allowance [see 13.10].

Note that an application may be examined prior to being laid open to public inspection under section 10 of the *Patent Act*, but the examiner will not approve the application for allowance until it has been laid open.

13.05.01 Identifying the invention

As noted in section 12.01 of this manual, an invention is a solution to a practical problem. In the words of the Supreme Court in *Apotex v. Wellcome*: the granting of patents is "a method by which inventive solutions to practical problems are coaxed into the public domain".[2]

13.05.01*a* Identifying the problem and its solution

The Office considers "a solution to a practical problem" to imply "a technological solution to a practical problem" or, equivalently, "a technological solution to a problem in a field of technology".

As noted in 12.02.01, the Office considers the term "field of technology" to refer to what the Courts have called the "useful arts" and the "manual and productive arts", but using language more reflective of modern industry. The term "technology" itself means "the application of scientific knowledge for practical purposes, especially in industry", "machinery and equipment developed from scientific knowledge", and "the branch of knowledge dealing with engineering or applied sciences".[3]

To understand what the inventors view as the problem and its solution, an examiner is guided by the application itself, since the applicant is required to set out in the description the technical field of the invention [paragraph 80(1)(*b*) of the *Patent Rules*], and the nature of the technical problem being addressed and the solution to that problem [paragraph 80(1)(*d*) of the *Patent Rules*].[4] Note that the terms "problem" and "solution" need not appear in the description. An applicant will often describe their invention in terms of its "objects", i.e. its purpose or goal.

The initial assessment of the problem and its solution is made without comparing the matter of the claim to the prior art. Identifying the solution being proposed by the applicant provides important context for examining the claims. Whether the solution being proposed in the application is patentable depends on it being statutory subject-matter that is novel, unobvious and useful.

A patentable invention may be an alternative solution to a known problem (such as an improvement over, simplification of, or selection from another invention) or a solution to an unresolved problem (which problem could be previously known or newly identified).

It is also possible for an application to disclose solutions to more than one problem. A preferred embodiment of an invention, for example, may solve not only the problem broadly addressed, but simultaneously address a further problem. Where an application discloses and claims more than one solution to a problem, or solutions to different problems, it is necessary to consider the requirements of unity of invention [see chapter 14 of this manual].

13.05.01*b* Examining the invention as claimed

Examination is guided by the claims, since the exclusive rights conferred by a patent apply only to subject-matter encompassed by the claims as understood by the person skilled in the art. The person skilled in the art will read the specification with "a mind willing to understand, not a mind desirous of misunderstanding".[5] As noted by the Supreme Court, "[a] 'mind willing to understand' necessarily pays close attention to the purpose and intent of the author".[6]

In interpreting the matter of the claims during examination, the purpose for which the invention was invented must be kept in mind. Each claim must define a solution to a practical problem and must be supported by the description. The solution defined in a given claim is that set of elements that are, together, necessary to provide a solution to a problem addressed by the inventors.[7] These are the "essential elements" of the invention. Identifying which disclosed solution the claim is directed to permits its essential elements to be identified. Since each claim may define a solution to a different problem than that solved by the subject-matter of other claims, each claim may have different essential elements than the other claims.

It is important to remember that the analysis to identify the essential elements is performed in view of the common general knowledge of the person skilled in the art but before the matter of the claim is compared to the teachings of the prior art.

During examination, the nature of the problem addressed and solution to that problem may be discussed in correspondence between the examiner and the applicant. A change in an examiner's understanding of the problem addressed by the matter of a claim may change their interpretation of which elements in that claim are essential for defining the solution to that problem.

A patentable invention must be a novel, inventive technological solution to a problem in a field of technology, and each claim in an application must be examined to determine whether it defines such subject-matter.

13.05.02 Form and substance examination

During examination, the subject-matter of each claim is considered from the perspective of both form and substance. By "form" is meant what the language of a claim, on its face, appears to be defining as the invention. By "substance" is meant the solution to a particular problem to which, in view of the specification as a whole, the applicant appears to be directing the claim.

Examination, as noted in 13.05.01*b*, is guided by the claims. Under "form and substance" examination, defects arising from either the form or the substance of a claimed invention may be identified in an examiner's report.

Defects related to the form of a claim are those that may be identified purely from an analysis of the language of the claim itself. Form-based objections can be made, for example, to certain defects arising from a claim's language, or where a claim is explicitly directed to non-statutory subject-matter.

Defects related to the substance of a claimed invention are those that may only be identified when the text of the claim is assessed in view of the description and/or the prior art and common general knowledge of the person skilled in the art. Substance-based objections can be made, for example, in respect of issues of proper support (written description or enablement), utility, novelty or obviousness of the claimed matter, or where the invention, in substance, is non-statutory.

Defects related to the form of a claim are identified regardless of the substance of the claim, while defects related to the substance of the invention may be raised, as circumstances dictate, regardless of the form of the claim [see, e.g., 13.05.03*b*].

Examination of the claims is performed on a claim-by-claim basis, but where a claim includes more than one complete, operable form of the invention each such embodiment must be considered independently. Where even a single embodiment in a claim is objectionable (e.g. for a lack of novelty, obviousness, lack of utility or for being non-statutory) an objection is made to the claim as a whole.

13.05.03 Patentability and contribution

To be patentable, an invention must fall within the definition of "invention" set out in section 2 of the *Patent Act*. That is, an invention must be statutory subject-matter and, further, must "fulfil the statutory requirements of novelty, ingenuity and utility".[8] The novelty, ingenuity, and utility of the invention must be common to a single set of elements that are, in combination, statutory subject-matter.

The novelty and ingenuity of an invention arise from a disclosure to the public of something they did not previously have, and which would not have been obvious in view of the information they had as of the claim date. This new and unobvious matter constitutes what the applicant has added to human knowledge, and is referred to as their "contribution".[9]

In order to determine what has been contributed, the subject-matter of a claim is generally compared to the relevant prior art and common general knowledge. An acknowledgement by the applicant of the state of the prior art, in respect of what is anticipated or obvious, is binding on the applicant.[10] Such statements therefore establish limits on the potential contribution. Similarly, a lack of detail in the description regarding some matter within a claim can be taken as an indication that the applicant considers that matter, or how to arrive at or operate that matter, to be known to the person skilled in the art.[11]

The utility of an "invention" arises from its being a technological solution to a practical problem.[12] As noted in 13.05.01*b*, the solution in a given claim is defined by that set of elements that are, together, necessary to provide a solution to a problem addressed by the inventors. These are the "essential elements" of the claimed invention, and it is these elements that must provide novelty and ingenuity to the matter of the claim.

These essential elements, as a set, also must be statutory subject-matter. That is, they must be, when considered in combination, a statutory art, process, machine, manufacture or composition of matter. A set of "essential elements" in a form that can interact with the physical world to provide a technological solution to a practical problem is called a "practical form" (or "practicable form") of an invention [see section 12.03 of this manual]. A "practical form" will, by necessity, include at least one physical element. An allowable claim must define a contributed, statutory "practical form" of an invention.

Since the patentability of a claim depends on statutory subject-matter having been contributed, it is not necessary during examination to determine whether or not a claimed non-statutory element has been contributed if that element does not form part of a statutory combination [see 13.05.03*a* and 13.05.03*b*]. Whether contributed or not, that element will not of itself lead to a patentable invention.[13]

When determining what within a claim has been contributed (i.e. is novel and unobvious), a set of elements that works together to achieve a specific result should be assessed by considering the set as a whole. This is to ensure that useful combinations are not inappropriately assessed by considering the novelty or ingenuity of their parts in isolation. Where mutually independent results are achieved by the operation of certain elements of a claim, however, the sets of elements responsible for each independent result should be considered separately. This is to avoid aggregations being improperly treated as if they were combinations.

For example, consider a claim to a high-powered car having good road adhesion, where the car is defined as comprising a certain engine and particular tires. The engine is responsible for an independent result (the high power), and should be compared to the prior art as a discrete combination (the engine itself being a set of elements that, together, are necessary to provide a specific result). The tires, being responsible for a different independent result (the road adhesion), should also be considered separately to determine if they are a contribution.

A set of elements is contributed when it is both novel and inventive. The inventive step associated with a novel set of elements can arise either from conceiving of that set of elements as being a solution to a particular problem, or from the activities necessary to reduce the idea of the set of elements to a practical form, or both.[14]

Where the invention resides in using something to solve a problem it wasn't known to solve (a new use for the thing), the application of the thing to the new purpose can be a contribution. Thus, even where a known article is used in new circumstances to achieve an unobvious result, there has been a contribution. The known thing cannot itself be claimed, but the new use can be. For further guidance on "use" claims, see section 12.06.06 of this manual.

13.05.03*a* Identifying statutory and non-statutory features

A claim will define its subject-matter in terms of one or more features, each of which limits the scope of the claim in some way. In order to determine whether the matter of a claim includes a statutory contribution, and hence a potentially patentable invention, it is necessary to identify which features (or elements; the two terms are interchangeable) within a claim are statutory subject-matter and which are non-statutory subject-matter.

A "non-statutory feature" is one that would be objected to as non-statutory if defined on its own in a claim, while a "statutory feature" (or "statutory element") means a material object (a machine, manufactured article or composition of matter) or a physical step in an art or process, other than one that is a "non-statutory feature" [see Chapter 12 of this manual for a discussion of statutory and non-statutory subject-matter].

The term "discrete element" is used to describe a feature or set of features whose role in achieving the objects of the invention can be considered independently of other features. Where a claim includes more than one feature, one feature may serve to limit the technological scope of another by further defining the characteristics or properties responsible for the practical utility of the feature being limited. In such cases, it is only the "so-limited feature" that is a discrete element of the claim. "A metal bar comprising a carbon-steel alloy", for example, is a single discrete element wherein the feature "carbon-steel alloy" limits the technological scope of the feature "metal bar". An element in a claim is not discrete, for the purposes of the invention defined by that claim, if it provides necessary definition to the technological nature of another element in that claim.

Where one feature does not provide a technological limitation to another, the two features should each be treated as a discrete element of the claim. "A DVD having a piece of music stored thereon", for example, contains two elements: the DVD, and the piece of music. The music does not limit the technological character of the DVD.

When analysing a claim to determine the nature of the contribution, the analysis is based on a consideration of the discrete elements. The "essential elements" of a practical form of a technological solution are that set of discrete elements that are necessary to define that solution.

Where a feature A limits the nature of a feature B, the resulting discrete element is of the type defined by feature B. Thus, the discrete element "a metal bar comprising a carbon-steel alloy" is a type of metal bar, not a type of carbon steel.

Where a non-statutory feature provides a technological limitation to a statutory feature, the resultant discrete element is statutory. Through the limitation, the technological properties or characteristics of the statutory element are further defined. Conversely, where a statutory feature provides a limitation to a non-statutory feature, the resultant discrete element is non-statutory.

A common "non-statutory feature" that appears often in claims is a formula or equation. A formula or equation is a "non-statutory feature" given that, in view of subsection 27(8) of the *Patent Act*, it would be non-statutory if claimed on its own [see section 12.05.01 of this manual]. In a claim, a formula may serve to limit the technological properties or characteristics of another feature. For example, in a method for synthesizing a chemical product, the act of adding one reagent could be performed according to an equation that governs how much of that reagent is added as a function of time. Presuming that the addition profile leads to a particular practical result, the step of adding the reagent is given a particular technological character by the equation. In this example, the "equation-limited step" is therefore a discrete, statutory element of the claimed method.

An example of a non-statutory feature limited by a statutory feature is a method of surgery performed using a particular surgical tool. Where the tool modifies the technological character of the surgical step, the discrete element of the claim is a "tool-modified surgical step", and is non-statutory [see section 12.05.02 of this manual]. This is so regardless of whether a valid claim could be made to the surgical tool itself; in the context of the method, the surgical tool is not a discrete element of the claim but rather is a modifier of a step in the method. The same analysis would apply, for example, to a claim to a mouse modified by a prosthetic. The "prosthetic-modified mouse" is a discrete, non-statutory element. Even where the prosthetic itself could be claimed as an invention, in the claim to the modified mouse it is not a discrete element of the claim, but rather a modifier of the mouse. The "modified mouse" would be rejected as non-statutory [see section 12.05.03 of this manual].

Where a claim includes a formula or equation as one of its features, it will generally be necessary to determine whether or not the formula or equation limits the technological scope of another feature in the claim. In the case of a chemical equation or formula, however, the conclusion is always that the chemical formula limits the characteristics or properties responsible for the utility of the composition of matter. Where a composition of matter defined by an equation or formula is a discrete element of a claim, it is statutory.

Note that, in identifying the statutory and non-statutory features, a discrete element can be defined by more than two features. For example, the "metal bar comprising a carbon-steel alloy" could be further defined in terms of the carbon-steel alloy having a formula X. The discrete element would then be the "metal bar comprising a carbon-steel alloy having the composition defined by formula X".

In considering whether one feature in a claim is modifying the technological properties of another, the purpose and nature of the claimed invention provide important context. In a method or process, for example, the essential elements are method steps. In a composition of matter, the essential elements are ingredients of the composition, and in a machine or article of manufacture the essential elements are components or parts.

The examples in of 13.05.03*c* illustrate the application of the foregoing analysis to specific cases.

13.05.03*b* Examination and the contribution analysis

In examining a claim, once the discrete elements of the claim have been identified, three cases can be encountered:

i) the claim includes only statutory discrete elements;
ii) the claim includes only non-statutory discrete elements or is otherwise excluded by its form; and
iii) the claim includes both statutory and non-statutory discrete elements.

Case i)

Where a claim includes only statutory discrete elements, the "contribution" analysis is, simply, the traditional analysis for novelty and obviousness [see Chapter 15 of this manual for further information on assessing novelty and obviousness]. It necessarily follows that any contribution that might exist would be statutory. If no contribution exists the claim is objectionable, e.g. under either section 28.2 or 28.3 of the *Patent Act*. If a contribution exists, and the claimed matter is useful, the claim defines a patentable invention.[15]

Case ii)

Where a claim includes only non-statutory discrete elements or is otherwise directed to non-statutory subject-matter by its form, the claim is objectionable under section 2 of the *Patent Act* [see Chapter 12 of this manual for a discussion of statutory and non-statutory subject-matter]. It is not necessary for the novelty or obviousness of the claimed matter to be evaluated; regardless of what within such a claim might have been contributed, the claim does not define a statutory "invention".

Case iii)

Where a claim includes both statutory and non-statutory discrete elements, the contribution analysis is focussed on determining whether or not the claim includes a statutory contribution.

As discussed in 13.05.03, for a claim to include a contribution it must define a novel and unobvious set of elements. For the claim to be patentable, the contributed subject-matter also must be useful and statutory. That is, the contributed element or combination of elements must provide a technological solution to a problem in a field of technology, and not be excluded subject-matter. As stated in 13.05.03, the contribution in a patentable claim must include a statutory "practical form".

If there is no statutory contribution, there is no statutory "invention" within the meaning of section 2 of the *Patent Act*. Where this is the case, the examiner's report should include a separate section that sets out the analysis whereby the statutory elements were determined not to be part of the contribution. Since this analysis will consider the novelty and obviousness of any statutory elements in the claim, it should be provided separately from any objection under section 2 of the *Patent Act* that arises from its conclusions, in order to avoid any confusion as to the basis of the objection.

A discrete non-statutory feature cannot itself result in a statutory invention. It is therefore not necessary to assess whether any discrete non-statutory features have actually been contributed. Where a claim includes a discrete non-statutory feature and it is concluded that no statutory contribution exists, the claim is objected to as defining matter that is not a statutory "invention" within the meaning of section 2 of the *Patent Act*. Such an objection is maintained as long as the discrete non-statutory feature remains in the claim, and regardless of whether or not it is actually a contribution.[16]

It should be clear from the objection that the defect is not that all the elements defined in the claim are non-statutory, but rather that, having determined that no statutory element is part of the contribution, any possible "invention" in the claim (being that of the non-statutory features) is non-statutory. As noted by the Federal Court of Appeal, the language of a claim is not to effect the "transforming into patentable subject-matter [of] what would, otherwise, be clearly not patentable".[17]

13.05.03*c* Examples

The following examples apply the guidance set out in 13.05.03*a* and 13.05.03*b* to various claims, to illustrate the application of this guidance in specific cases.

Examples:

1. An application discloses compositions for stimulating hair growth. Prior art document D1 discloses certain medicinal compositions and discloses and exemplifies compositions which fall within the scope of claim 1.

Claim:

> 1. A composition comprising a compound defined by the chemical formula (I) and an acceptable carrier therefor.

Analysis: At the outset, the claim could appear to include three features - the compound, the chemical formula (I) and the carrier. The formula, on its own, would be a non-statutory feature and it is therefore necessary to understand its effect in the claim. The chemical formula (I) serves to define the technological nature of the composition of matter it modifies, and the compound defined in terms of chemical formula (I) is a statutory element of the claim. It is worth noting that this is always the appropriate conclusion when a chemical formula is used to limit a composition of matter to yield a discrete element of a claim. The claim also includes a second statutory element, this being the carrier. The claim therefore includes two discrete statutory elements and, for the purposes of examination, falls into case i). In view of D1, the claim does not make any contribution. It teaches only an old solution - the known composition. The claim is objectionable under section 28.2 of the *Patent Act*.

Summary: Case i); the claim includes two discrete statutory elements. No contribution in view of the prior art. The claim is objected to for lack of novelty.

2. An application discloses a method for manufacturing tires, and discloses an equation to calculate how much vulcanizing agent should be added as a function of time in order to improve the cure of the rubber. The prior art does not disclose or make obvious to vulcanize tires in the manner proposed, and the description supports the promised advantages of the modified process.

Claim:

> 1. In a process for vulcanizing tires, the improvement wherein the addition of a sulfur-based vulcanizing agent is made according to equation (1).

Analysis: Equation (1) could not be claimed on its own, and is therefore a non-statutory feature. In the claim, however, it serves to limit the nature of a physical step in the process (the step of adding vulcanizing agent), such that the step is made suitable for solving the practical problem set out in the application (i.e. the technological character of the step is modified by the equation). The physical step of addition practised according to the limits established by equation (1) is a single discrete element of the claim. The claim therefore includes only a single discrete, statutory element and, for the purposes of examination, falls into case i). The claim contributes a statutory element, and the modified process is a practical form - it can be used to achieve the promised utility. The claim therefore defines a patentable invention.

Summary: Case i); the claim includes a single discrete statutory element (a modified statutory method step). The claim is allowable.

3. An application discloses that a particular woodworking tool makes it easy to inscribe complicated patterns on work pieces. The tool combines features previously known in two separate woodworking tools disclosed in documents D1 and D2. It provides only the aggregate advantage of the two known tools.

Claims:

1. A woodworking tool comprising a hooked blade having an offset point, said blade being attached via a locking ball joint to an ergonomic handle.
2. A dining table inscribed with a pattern produced by scribing using the woodworking tool of claim 1.

Analysis: Claim 1 defines a woodworking tool having three discrete statutory elements - the blade, the locking ball joint, and the handle. These operate together as a set to provide the promised utility of the invention. The claim includes only statutory elements and, for the purposes of examination, falls into case i). In view of D1 and D2, the examiner concludes that there is no ingenuity in the tool, and the claim is objected to under section 28.3 of the *Patent Act*.

Claim 2 contains two features, these being the table and the pattern inscribed by the tool. The table is a statutory element, and the pattern is a non-statutory feature having a purely aesthetic significance. The pattern does not change the practical utility of the table, i.e. its technological character. Note that the woodworking tool is not an actual feature of the claim, since it does not limit the nature of the inscribed pattern. In the present case, the feature "a pattern" has the same scope as "a pattern produced by scribing using the woodworking tool of claim 1". The claim therefore includes both a statutory (the table) and a non-statutory (the pattern) discrete element and, for the purposes of examination, falls into case iii). Tables unquestionably forming part of the common general knowledge, the table itself has not been contributed. The claim consequently does not include a statutory contribution, but does include a discrete non-statutory feature - the pattern. The examiner sets out this analysis in their report. An objection is made to the claim under section 2 of the *Patent Act* for not defining a statutory "invention".

Summary: Claim 1 belongs to case i); it contains three discrete statutory elements. There is no contribution in view of the prior art. The claim is objected to for obviousness. Claim 2 belongs to case iii); it contains a discrete statutory element (the table) and a discrete non-statutory element (the pattern). The table is not a contribution, therefore the claim is objected to, in view of the pattern, for not defining a statutory "invention".

4. An application discloses a genetically-modified mouse that is predisposed to certain cancers of the liver. The mouse is modified by the introduction of recombinant DNA into its genome, thereby causing the predisposition to cancer. The application also teaches how the mouse can be used to screen for drug candidates to treat those cancers, using a known screening technique disclosed in several documents.

Claims:

1. A recombinant vector comprising a DNA molecule defined by SEQ ID NO: 1.
2. A transgenic mouse having a genome comprising the recombinant vector of claim 1.
3. A method for screening drug candidates for anticancer activity in the liver, said method comprising the steps of: (a) providing a mouse according to claim 2 that exhibits liver tumours; (b) injecting said mouse with a dose of a drug candidate; (c) monitoring the size of liver tumours over the course of 1 week; (d) identifying drug candidates that reduce the size of said liver tumours by at least 5% by volume.

Analysis: Claim 1 defines a composition of matter (the vector) defined in terms of DNA that is itself defined in terms of the sequence provided by SEQ ID NO: 1. As noted in 13.05.03*a*, a composition of matter limited by a chemical equation or formula is a statutory element. The DNA is therefore limited in a technological manner by the limitation on its sequence listing, and the recombinant vector as a composition of matter is limited in a technological way by inclusion therein of the DNA. The claim includes a single discrete, statutory element (the vector modified by the DNA defined by the sequence) and, for the purposes of examination, falls into case i). Presuming the promised utility has been established, the patentability of the vector depends on it being a contribution (i.e. that the vector is novel and unobvious).

Claim 2 on its face is directed to a mouse. The claim therefore belongs to case ii), since the claim, by its form, is directed to a higher life form. The claim will consequently be objected to under section 2 of the *Patent Act*. Although it is not necessary to perform a more complete analysis of the claim, such an analysis would arrive at the same conclusion. The claim could initially be interpreted as defining three features - a mouse, a genome and the vector of claim 1. The vector provides a technological limitation to the genome, and these two features can initially be considered to together form a single element - the modified genome. The modified genome, in turn, provides a technological limitation to the mouse, and the claim therefore defines only a single discrete feature, being the "genome-modified mouse". As noted at the outset, mouse is, by its form, non-statutory, and the claim consequently falls into case ii) and is objected to under section 2 of the *Patent Act*. Whether or not the mouse is a contribution (i.e. is novel and unobvious) is not material to the examination of claim 2.

Claim 3 defines a method that requires several steps that together provide a technological solution. The method is best considered not as a series of individual steps, but as a combination. Ignoring the mouse for the moment, the method itself involves physical manipulations that satisfy the basic requirement set out in section 12.02.01 of this manual. That is, it is a method that includes "an act or series of acts performed by a physical agent on a physical object and producing in that object some change of either character or condition". The method, considered as a series of generic steps unmodified by the mouse, is a statutory set of elements. The claim also includes a non-statutory feature, since it depends on the presence of the mouse of claim 2. The mouse has the effect of changing the technological character of the method, since it causes the method to screen specifically for drug candidates for treating cancers of the liver. The mouse, therefore, is not a discrete element of the method claim, but rather modifies the statutory method to give it a distinct technological character. A statutory method step modified in a technological manner by a non-statutory feature remains a statutory method step [see 13.05.03*a*]. The statutory nature of the method as a whole therefore remains unchanged, and the claim, for the purposes of examination, falls into case i). Note that the proper conclusion is reached by bearing in mind that the claimed invention is a method with a specific purpose. The elements necessary for the method to provide its promised utility are its steps. The mouse, as a feature of the claim, serves to limit the technological scope of certain essential method steps such that a specific practical result can be achieved. It is the "mouse-modified steps", and not the mouse itself, that are the discrete elements of claim 3. If the purpose of the method is ignored, the conclusion reached could be that the mouse is a discrete element of the claim, and that only the mouse, rather than the method as a whole, is the contribution. This could lead to the incorrect conclusion that the claimed invention is non-statutory.

Summary: Claim 1 belongs to case i); it defines a single discrete statutory element. The claim would be examined for novelty and obviousness (i.e. for a contribution) and for utility. Claim 2 belongs to case ii); it defines a single discrete non-statutory element. The claim is objected to under section 2 of the *Patent Act*. Claim 3 belongs to case i); it defines a single statutory set of elements (the method). The claim would be examined for novelty and obviousness, and for utility.

5. An application discloses a set of match-making criteria to be used in matching members of a dating service. The computer is a general purpose machine, and the technological approach to querying storage locations, transferring data, and performing logic functions are known. The algorithm used in match-making is the result of extensive empirical studies of interpersonal behaviour and is asserted as leading to matches with greater compatibility.

Claim:

1. A computer adapted to identify interpersonal compatibility by comparing variables associated with a first party and variables associated with an nth party according to the weighting scale defined by the following criteria [X, Y, Z] and to display the n best matches, wherein the computer obtains a variable (1a) regarding the first party from a first storage location, and variable (na) regarding the n^{th} party from an n^{th} storage location, ...

Analysis: Claim 1 includes two features, these being the computer and the algorithm that has adapted it to implement the match-making. The algorithm itself is a non-statutory feature. The algorithm (implemented as software) for identifying interpersonal compatibility does not modify or limit the computer in a way that provides a technological solution to a practical problem. It is therefore concluded that the two features of the claim are discrete. The computer itself is a statutory discrete element, and the algorithm is a non-statutory discrete element. The claim belongs to case iii). The computer itself is a known general purpose machine, and does not form part of the contribution. The claim therefore does not include a statutory contribution, but does include a discrete non-statutory feature - the algorithm. It is not necessary for the examiner to determine whether the non-statutory feature is novel or inventive. In objecting to the claim, the examiner would provide their contribution analysis, setting out how they determined that the computer is not part of the contribution (i.e. is not novel and inventive). An objection to the claim would be made, setting forth that, in view of the contribution analysis, it does not define a statutory "invention" within the meaning of section 2 of the *Patent Act*.

Summary: Case iii); the claim includes a discrete statutory element (the computer) and a discrete non-statutory element (the algorithm). The computer not being a contribution, the claim is objected to in view of the algorithm for not defining a statutory "invention".

6. An application discloses a particular coating for seeds, that prevents early germination and frost damage. The application is sufficient to support the utility of the coating and the coated seeds. The coated seeds are novel and not obvious in view of the prior art.

Claims:

1. A coating composition for coating seeds, comprising [several components].
2. A seed coated with a coating as defined in claim 1.
3. An agricultural product comprising a seed coated with a coating composition as defined in claim 1.
4. A process for producing a coated seed, comprising the steps of: i) providing a supply of seeds; ii) providing a supply of a coating material as defined in claim 1; iii) coating the seeds with the coating material.

Analysis: Claim 1, presuming the components to be chemical products, includes only a set of discrete statutory elements. The claim falls in case i). Since the utility of the seeds is supported by the application, the utility of the composition is a given. The patentability of the composition consequently depends only on its novelty and ingenuity.

Claim 2 is directed to a higher life form (a seed) and is excluded by its form. The claim therefore belongs to case ii), and is objected to as such. Although unnecessary to do so, this conclusion can be confirmed by initially considering the claim to include a non-statutory feature (the seed) and a statutory element (the coating composition). Recognising that the coating modifies the technological properties of the seed, it is correctly concluded that the claim includes a single non-statutory discrete element - the coated seed.

In the case of claim 3, merely calling the seed an "agricultural product" does not alter that the claim is directed to a coated seed *per se*. The same analysis as provided for claim 2 applies to claim 3.

Claim 4 can be analysed in a manner similar to the method of example 4. The steps of the method (providing a substrate, providing a coating material, coating the substrate with the material) are best considered not as a series of individual steps, but as a combination. Ignoring the seed for the moment, the method itself involves physical manipulations that satisfy the basic requirement set out in section 12.02.01 of this manual. That is, it is a method that includes "an act or series of acts performed by a physical agent on a physical object and producing in that object some change of either character or condition". The method, considered as a series of generic steps unmodified by the seed, is a statutory set of elements. The claim also includes the seed, which is itself a non-statutory feature. In the claim, however, it serves to limit the technological scope of the method, such that the nature of the product being manufactured is controlled. A statutory method whose technological scope is modified by a non-statutory feature remains a statutory method [see 13.05.03*a*]. The claim, for the purposes of examination, falls into case i). Given that the coated seeds are novel and unobvious, it follows that the process to produce the seeds has been contributed and that this claim includes a patentable invention. Note that absent claim 4, it would not be necessary to assess the novelty or obviousness of the seeds. In assessing whether the method has been contributed, however, the search would uncover whether the coated seeds are known or obvious. Note also that the fact that the process produces a non-statutory product does not cause the process itself to be non-statutory [see section 12.02.02 of this manual].

Summary: Claim 1 belongs to case i); it includes only statutory discrete elements. Patentability depends on novelty and ingenuity (utility having been established in the present example). Claims 2 and 3 belong to case ii); they include only a non-statutory discrete element, and are objected to for under section 2 of the *Patent Act*. Claim 4 belongs to case i); it includes only statutory discrete elements, since the non-statutory feature is merely a limit on the technological scope of the statutory method. The method is found to be patentable.

7. An application discloses a method for diagnosing disease X in a human, wherein the method involves screening blood or liver tissue for a particular antibody Z whose presence indicates that the patient has disease X. The correlation between antibody Z and the disease was not previously known, and nothing in the prior art suggests that it had ever been screened for before.

Claims:

1. A method of diagnosing a patient for disease X, comprising the steps of:
    (a) removing a sample of blood from the patient;
    (b) screening the sample for the presence of antibody Z;
    (c) determining whether the patient has disease X on the basis of the presence or not of antibody Z.
2. A method of diagnosing a patient for disease X, comprising the steps of:
    (a) removing a sample of liver tissue from the patient;
    (b) screening the sample for the presence of antibody Z;
    (c) determining whether the patient has disease X on the basis of the presence or not of antibody Z.

Analysis: Claim 1 includes steps (a) and (b) that are physical steps, and step (c) that is a mental step of data analysis. Each step of the method is a discrete element, and the set of elements as a whole does not treat a medical condition. The claim is not, on its face, directed to a method of medical treatment, and is not excluded by its form. Steps (a) and (b) are statutory steps [drawing blood is not considered a surgical intervention; see section 17.02.03 of this manual], whereas step (c) is a mental process (drawing a conclusion by analysing data) and is itself non-statutory. The claim therefore belongs to case iii). Patentability of this claim therefore depends on whether or not it includes a statutory contribution. The technological scope of step (b) is modified by antibody Z. Given that this species had never been screened for before, step (b) has been contributed and provides a technological solution to the practical problem of identifying the presence of the antibody in the blood. The claim, presuming utility, is therefore allowable.

Claim 2 also includes three steps, but in its case step (a) is an excluded surgical manipulation (excising tissue from a patient's liver). The set of elements as a whole is therefore an excluded method of surgery, and belongs to case ii) [see section 17.02.03 of this manual].

Summary: Claim 1 includes both statutory discrete elements and non-statutory discrete elements, and belongs to case iii). Since one of the statutory discrete elements is contributed, the claim (presuming utility) is allowable. Claim 2 also includes both statutory and non-statutory discrete elements. Its discrete elements, as a set, define an excluded method of surgery, and the claim therefore belongs to case ii) and is objected to for being directed to non-statutory subject-matter.

8. In *Schlumberger Canada Ltd. v. Commissioner of Patents*[18] the Federal Court of Appeal was asked to pronounce on the patentability of a process in which calculations were made, by way of a computer, according to certain new formulae. The Patent Appeal Board considered a set of claims with two independent claims, and the Commissioner of Patents accepted the recommendation that these claims be refused. The application taught that the calculations performed (the "machine combining" of data) are best carried out on a programmed general purpose computer. In upholding the Commissioner's decision, the Federal Court of Appeal commented that "it is obvious, I think, that there is nothing new in using computers to make calculations of the kind that are prescribed by the specifications. It is precisely in order to make that kind of calculation that computers were invented. What is new here is the discovery of the various calculations to be made and of the mathematical formulae to be used in making those calculations. This is not, in my view, an invention within the meaning of s. 2."

Claims:

1. A machine operated method of processing well logging data, comprising:
    (a) deriving a plurality of measurements [...];
    (b) machine combining at least some of said derived measurements [...] to compute at least one input parameter [...];
    [steps (c) and (d) are equivalent to step (b), but calculate different quantities.]

46. Apparatus for processing well logging data [...] comprising:
    (a) means for deriving a plurality of measurements [...]
    (b) a data processing unit; and
    (c) means adapted to control said data processing unit [according to the method of claim 1].

Analysis: The following analysis sets out how the above claims could be approached using the guidance set out in this chapter, and is provided to highlight the similarity of this approach to the analysis performed by the Court.

Claim 1 defines a method for obtaining and machine processing data. Step (a) of the claim appears to be statutory (the acts of obtaining data are presumed to be physical). The "machine combining data" steps involve, when understood in view of the description, a general purpose computer performing calculations. The data being combined does not limit the technological properties of the computer as it performs the acts of "machine combining", and steps (b) through (d) therefore include both statutory features (the technological act of machine combining) and non-statutory features (the acts of combining data to calculate parameters). The claim therefore falls into case iii). In view of the state of the art, it was concluded that neither the collecting of data [i.e. the acts of step (a)] nor the manner by which the computer performed the "machine combining" were new. Consequently, the claim was found not to include a statutory contribution. The calculations to be performed, of themselves, are non-statutory; they are not a patentable invention. The claim would be objected to for not defining a statutory "invention" within the meaning of section 2 of the *Patent Act*.

Claim 46 defines an apparatus, and appears to have been construed during its actual prosecution as defining a programmed general purpose computer. Feature (a), and its relationship to the claimed apparatus, was not directly discussed when considering the claimed apparatus in the actual prosecution, and for consistency it will not be considered in this analysis. As a starting point, the claim is therefore taken to define a computer programmed to perform certain calculations. Feature (b) (the data processing unit) is a statutory element. Feature (c) is understood in the present context to be a computer program that will cause the computer to carry out the calculations (the "machine combining") set out by the method of claim 1. The calculations manipulate data to extract more meaningful information from the data. Neither the calculations nor the formulae embodying them are, of themselves, statutory. They do not control the computer so as to provide a technological solution to a practical problem. Since, in the present case, feature (c) does not limit the technological properties of the data processing unit (b), features (b) and (c) are both discrete. The claim falls into case iii). It is admitted in the application's description that the data processing unit (b) is a known device (a general purpose computer), and therefore it does not form part of the contribution. As noted above, the act of combining data according to an algorithm or equation is not of itself statutory. The claim consequently does not include a statutory contribution, and is objected to for not defining a statutory "invention" within the meaning of section 2 of the *Patent Act*.

Summary: Claims 1 and 46 both include both statutory and non-statutory discrete features and belong to case iii). Upon analysis, the statutory features are determined not to be contributed, and the claims, in view of the discrete algorithm feature, are consequently objected to for not defining a statutory "invention".

9. In *Lawson v. Commissioner of Patents*[19] the court considered a claim to parcels of land subdivided according to a particular plan. The inventor proposed to subdivide land such that the individual parcels of land had legal boundaries defined by the shape of a champagne glass. During the case, all parties agreed that a claim to the land *per se* was untenable. The court consequently proceeded "[o]n the assumption that what is being applied for is a patent for a method". The court, therefore, determined to consider the substance of the

invention rather than the language of the claim. In assessing whether or not there was a patentable method, the court noted that the subdivided land itself was unchanged in its character (i.e. not "new"). This led to the conclusion that any novelty was resident in the plan for subdividing, which plan is not of itself statutory matter.

Claim:

1. In the art of municipal development the improvement which consists in a subdivided parcel of building land [...] (the claim then defining the shape of the legal boundary)

5. A subdivided parcel of building land as defined in claim 1 [...]

Analysis: This case is an example of the Courts rendering judgement on the substance of the alleged invention rather than on the basis of the form of the claims under consideration.

Claims 1 and 5 both define a parcel of building land defined in terms of its legal boundaries. The claims could be considered to include two features - land, which for the present analysis is presumed to be statutory as either a composition of matter or a manufacture, and the legal boundary, which is a feature having solely intellectual significance and is of itself non-statutory [see section 12.06.01 of this manual]. The legal boundary does not provide any technological limitation to the land itself, and the claims consequently include both statutory and non-statutory discrete elements and fall into case iii). Since a parcel of land is clearly not a contribution (this could be argued to be common general knowledge and would not require any prior art to be cited to support the point), the claims would be objected to for not defining a statutory "invention" within the meaning of section 2 of the *Patent Act*.

If a claim had been drafted as a claim to a method for subdividing land, this method would be non-statutory on its face, regardless of whether or not it would make use of any patentable technology. Following 12.04.02, the method would have significance only in respect of human law, and would not be a method in a field of technology. Such a claim would belong to case ii).

Summary: Claims 1 and 5 both include statutory discrete element (the parcel of land) and a non-statutory discrete element (the legal boundary), and fall into case iii). The land itself not forming part of the contribution, the claims are objected to in view of the legal boundary feature, on the grounds that they do not define a statutory "invention".

13.05.04 Search of the prior art

Patentability must be assessed in view of the prior art, and it is therefore necessary for the relevant prior art to be identified. The prior art, broadly speaking, includes everything known, in Canada or elsewhere, at the claim date.[20] In practice, however, the prior art relied on generally comprises only published patent documents, journal articles, textbooks, manuals and the like.

An application for patent in Canada may result from a national filing or from entry into the national phase of an international application filed in Canada or elsewhere under the Patent Cooperation Treaty (PCT).

The scope of the search of the prior art performed by a Canadian examiner at the national phase is determined in part by the extent to which relevant prior art has been identified in any earlier searches.[21] Further, examiners are not required to search claimed matter that is determined to be non-statutory, to lack practical utility or that is not supported by the application as filed (e.g. where new matter has been introduced contrary to subsection 38.2(2) of the *Patent Act*).

Where claimed matter is not required to be searched for any of the foregoing reasons, but it is evident from the specification as a whole that a claim to related subject-matter requiring a search could be made, a search should generally be performed on this related matter. By way of example, a claim to a method of medical treatment need not be searched, but if it is clear that a "use" claim could be made on related matter, the "use" should be searched.

Where the claimed subject-matter has been the subject of a comprehensive international search by an International Searching Authority, as regards that subject-matter a Canadian examiner will nevertheless perform at least a search of Canadian patent documents covering the five-year period prior to the application's filing date. The principal purpose of such a search is to identify Canadian patent documents relevant to double-patenting or, by virtue of their claim date, to anticipation under the first-to-file system (that is, under paragraphs 28.2(1)(*c*) and 28.2(1)(*d*) of the *Patent Act*).

It is usual for a Canadian examiner to consider all available foreign search results to avoid unnecessary replication of work. Where the results of a foreign search are relied on in a report, the report should indicate which documents were identified in a foreign search.

Where, for whatever reason, the examiner deems a further search would be appropriate, a comprehensive search is undertaken. This search need not be restricted to Canadian patent documents, but can be performed on any database to which the examiner has access. Of principal relevance are the databases of the EPO, USPTO and the Japanese and Korean patent offices. Examiners also have access to certain commercial databases.

Searches are generally limited by some combination of dates, keywords, and International Patent Classification (IPC) codes of relevance to the claimed matter. Examiners are not, as a general rule, required to indicate any details of their search strategy in their reports.

In keeping with the purpose of an examiner's report, it is desirable for all relevant prior art to be identified at the time of the first report. Nevertheless, particularly given the sheer quantity of prior art now available and practical limitations on the time an examiner can spend on an application, it must be acknowledged that in practice documents may be missed, or that at the early stages of examination the relevance of some documents may not be fully appreciated. It is also possible that, in view of amendments to the claims or arguments presented by the applicant, it becomes necessary to rely on additional prior art.

Where, for any reason, relevant prior art is identified during the course of prosecution, it is incumbent on the examiner to cite this prior art against the claimed invention.

13.06 Examiner's reports

An examiner's report is the official means of communication between an examiner and an applicant. It may contain one or more requisitions as well as information provided to clarify the scope or content of the requisition(s). The report will begin with a conspicuous (usually entirely in majuscule letters) opening paragraph informing the applicant of how many requisitions it contains (identified by bullets) and under which authority each requisition is made. It will also indicate the time limit to respond [see Chapter 20 of this manual for a complete discussion on time limits].

Each requisition made in a report must be responded to within the time period indicated in the report or the application will be abandoned in accordance with paragraph 73(1)(*a*) of the *Patent Act*. For each requisition on the basis of which the application was deemed to be abandoned, a specific request for reinstatement must be made, a separate reinstatement fee must be paid, and the necessary action taken to comply with the original requisition.

Under subsection 30(2) of the *Patent Rules*, where an examiner has reasonable grounds to believe that an application does not comply with the *Patent Act* and *Patent Rules*, the applicant must be informed of the application's defects and must be requisitioned to amend their application to comply or to provide arguments as to why the application does comply. The identification of all the defects the examiner was able to identify forms, for the purposes of paragraph 73(1)(*a*) of the *Patent Act*, a single requisition.

The beginning of this requisition can generally be identified in a report by text such as "the examiner has identified the following defects in the application:". The requisition ends with a paragraph such as "in view of the foregoing defects, the applicant is requisitioned, under subsection 30(2) of the *Patent Rules*, to amend the application in order to comply with the *Patent Act* and the *Patent Rules* or to provide arguments as to why the application does comply".

If the report includes additional requisitions, these will usually come after the 30(2) requisition. Other requisitions that may be present in an examiner's report are requisitions under section 29 of the *Patent Rules* (pertaining to the identification of prior art), requisitions under section 89 of the *Patent Rules* (pertaining to the provision of certified copies of priority documents), and requisitions under section 104.1 of the *Patent Rules* (pertaining to inclusion in the description of the date of deposit of biological material).

An examiner's report will usually include additional content that does not form part of a requisition, but which provides useful information regarding the report. This content, which may be called the preamble, will occur after the opening paragraph of the report and before the first requisition. Typically, the preamble of the report will indicate the date of the most recent amendments and, in the case of a first report, their origin (international stage or national stage), an indication of the number of claims on file, a statement regarding the search performed, and an identification of documents discovered and a discussion of their contents (if any).

Particularly where there is a question regarding unity of invention, the preamble will indicate to what extent the application has been searched and examined. If, in response to a unity of invention objection, an applicant appears to have limited the claims to one invention only (e.g. by selecting one of the identified groups, or by amending the claims in such a way that only a single invention is defined), this will be indicated in a subsequent report (if any).

The preamble may also include general comments on the prosecution and discussions relating to points raised by the applicant in their correspondence.

13.06.01 Withdrawal of an examiner's report

An examiner's report may be withdrawn where it is determined that the content of the requisition is inapplicable or unnecessary.

Such may be the case, for example, where an examiner's report and an applicant's amendment cross in the mail, and the report is by consequence no longer accurate.

Where an examiner's report is to be withdrawn, the examiner will inform Examination Support, who will cancel the report, remove the due date and inform the applicant in writing that the report is withdrawn. The examiner may also inform the applicant by telephone, as a courtesy and to prevent confusion and unnecessary work.

13.07 Amendment of the application

Section 38.2 of the *Patent Act* provides that the specification and drawings of an application may be amended before a patent is issued.

Any such amendment may not introduce any matter not reasonably to be inferred from the specification or drawings as originally filed ("new matter"), except in so far as it is admitted in the specification that the matter is prior art with respect to the application.

Amendments made subsequent to the sending of a notice of allowance and especially subsequent to the payment of a final fee are subject to certain limitations as discussed in 13.10 and 13.11.

Amendments must be submitted in the form of replacement pages, as the Patent Office will not amend the content of individual pages.

In accordance with section 34 of the *Patent Rules*, any amendment must be accompanied by a statement explaining the nature and purpose of the amendment.

An amended application is subject to further examination.

Amendments to an application are discussed fully in chapter 19 of this manual.

13.08 Final Action

In the course of examination, it will sometimes be that an impasse occurs between an applicant and an examiner as regards certain perceived defects of the application.

Where this is the case, the examiner may, in accordance with subsection 30(4) of the *Patent Rules*, write a "Final Action" on the application in which they set out all the outstanding defects and in which they reject the application under subsection 30(3) of the *Patent Rules*.

Final action practice is covered in chapter 21 of this manual.

13.09 Refusal to grant a patent

Section 40 of the *Patent Act* stipulates that whenever the Commissioner is satisfied that an applicant is not by law entitled to be granted a patent, the application shall be refused.

A registered letter addressed to the applicant or to the agent of record is sent, notifying the recipient of the refusal and of the reason therefor.

Typically, refusal of an application occurs subsequent to the sending of a final action and on the recommendation of the Patent Appeal Board. The refusal will usually include the heading "Decision of the Commissioner of Patents" and will include a complete explanation of the grounds for refusal.

Commissioner's Decisions, whatever the decision (full or partial refusal of the application or overturning of the examiner), are numbered sequentially and, except in the case of a decision to refuse an application filed prior to October 1, 1989 where the applicant did not give permission for the Office to publish the decision, are publicly available via the Office's web site at http://patents.ic.gc.ca/cipo/comdec/en/search.html.

In accordance with section 41 of the *Patent Act*, a refusal of the Commissioner may be appealed to the Federal Court within six months after the date of mailing of the decision.

13.10 Allowance and notice of allowance

Subsections 30(1) and 30(5) of the *Patent Rules* provide that where an examiner has reasonable grounds to believe that an application complies with the *Patent Act* and *Patent Rules*, the Commissioner shall notify the applicant that the application has been found allowable.[22]

The process within the Office is that an examiner approves an application for allowance. Patent Operations then checks the application to ensure certain formal requirements are met, and subsequently issues a notice of allowance requisitioning payment of the applicable final fee set out in item 6 of Schedule II within six months.

The application is "allowed" on the date at which the notice of allowance is sent.

Once an application is allowed, prosecution before the examiner has technically ceased. Amendments after allowance are, in accordance with subsection 32(2) of the *Patent Rules*, not permitted if they would require a further search by the examiner or if they would make the application not comply with the *Patent Act* and *Patent Rules*. Further, in accordance with subsection 32(1) of the *Patent Rules* an amendment after allowance may only be made upon payment of the fee set out in item 5 of Schedule II unless the amendment is to correct a clerical error that is obvious on the face of the application.

Failure to pay the final fee will result in abandonment in accordance with paragraph 73(1)(*f*) of the *Patent Act*. An application that has been reinstated after being abandoned for failure to pay the final fee may be amended, and is subject to further searching and examination before a new notice of allowance is sent.

Note that where an application is abandoned for failure to pay the final fee, paragraph 30(10)(*a*) of the *Patent Rules* provides that upon reinstatement the previous notice of allowance is deemed never to have been sent. In accordance with paragraph 30(10)(*b*) of the *Patent Rules*, a further notice of allowance will not requisition payment of the final fee unless the final fee submitted to effect reinstatement has been refunded or was not, in view of amendments changing the number of pages in the allowed application, sufficient.

13.11 Withdrawal from allowance

Subsection 30(7) of the *Patent Rules* provides that if, after a notice of allowance is sent but before a patent is issued, the Commissioner has reasonable grounds to believe that the application does not comply with the *Patent Act* or *Patent Rules*, the Commissioner shall notify the applicant of that fact, withdraw the notice of allowance, refund the final fee (if it has been paid), and return the application to the examiner for further examination.

The notice of allowance is deemed never to have been sent, nor (if applicable) the final fee to have been paid, and the provisions of sections 32 and 33 of the *Patent Rules* do not apply.

An application may be withdrawn from allowance, for example, in view of applicable prior art identified in a protest or in a filing of prior art under section 34.1 of the *Patent Act*.

13.12 Issuance of a patent

Upon payment of the final fee referred to in 13.10, the Office will process the application to grant, and will generally issue the patent on a Tuesday approximately nine weeks after payment of the final fee. The patent will issue in the name(s) of the inventor(s), or to the legal representative(s) on the basis of appropriate documentation such as assignments received no later than the day on which the final fee is paid.

In accordance with subsection 33(1) of the *Patent Rules*, where the final fee has been paid on an allowed application and has not been refunded, no amendment may be made to the application except where the final fee was paid to reinstate an application previously abandoned in accordance with paragraph 73(1)(*f*) of the *Patent Act* for failure to pay that final fee, and prior to a new notice of allowance being sent.

Under paragraph 4(10)(*b*) of the *Patent Rules*, a final fee may be refunded if the request for refund is received before the technical preparations for issue are begun.[23]

Where a patent issues from an application filed prior to October 1, 1989, it will receive a patent number in the 1,000,000 series. For applications having an application number in the 2,000,000 series, the issued patent will bear the same number as the application.

Endnotes for chapter 13

1. Applications are assigned to an examiner working in the field to which the claimed invention belongs, and are examined sequentially, within the applications assigned to a given examiner, according to the request for examination date.

2. *Apotex Inc. v. Wellcome Foundation Ltd.* [2002] SCC 77 [(2002), 21 C.P.R. (4th), 499 (S.C.C.)] at paragraph 37.

3. "Technology *noun*", *The Oxford Dictionary of English (revised edition)*, Oxford University Press 2005.

4. This guidance is only required of applications filed on or after October 1, 1996.

5. *Whirlpool Corp. v. Camco Inc.* [(2000), 9 C.P.R. (4th), 129 (S.C.C.)] at paragraph 49; citing *Lister v. Norton Brothers and Co.* [(1886), 3 R.P.C. 199, (Ch.D.)] at page 203. The actual quote from *Lister* is that a patent "must be read by a mind willing to understand, not by a mind desirous of misunderstanding".

6. *Whirlpool* (supra at 5) at paragraph 49

7. The term "set of elements" must be understood to include a set of one. The use of the term "together" is relevant only for a set of two or more elements.

8. *Biolyse Pharma Corporation v. Bristol-Myers Squibb Company* [2005] SCC 26 at paragraph 1

9. The approach set out in 13.05.03 is conceptually similar to the *Aerotel/Macrossan* (*Aerotel Ltd. v. Telco Holdings Ltd. & in the Matter of: Patent Application GB 0314464.0 of Macrossan* [2006] EWCA Civ 1371) "contribution approach" made use of in the UK, and the use of the term "contribution" will inevitably draw comparisons. The present approach, however, is distinct and cannot be directly related to the UK practice. The analysis, and the conclusions reached, in some ways also resemble the approach in the *Hitachi* decision [(2004) T258/03] followed by the EPO. It is important for the reader not to import into the present explanation any presumption that the practice being described is intended to mirror either *Aerotel* or *Hitachi*. Important distinctions exist, and the present approach is based solely on an assessment of Canadian jurisprudence.

10. *Shire Biochem Inc. v. Apotex Inc.* [2008] FC 538 at paragraph 25; *Eli Lilly Canada Inc. v. Novopharm Ltd.* [2007] FC 596 at paragraph 142; *Pfizer Canada Inc. v. Novopharm Ltd.* [2005] FC 1299 at paragraph 78; *Whirlpool Corp. v. Camco Inc.* [(1997), 76 C.P.R. (3rd), 150 (F.C.T.D.)] at page 186

11. Whether the applicant is correct to consider the matter to be known to the person skilled in the art is addressed when considering sufficiency of disclosure.

12. To be "useful" in the sense required by the *Patent Act*, the various requirements set out in Chapter 12 of this manual must all be met.

13. The differences between the present approach and the *Aerotel/Macrossan* and *Hitachi* approaches (see supra at 9) can be summarised as follows: in *Aerotel* one determines what has been contributed and asks whether it is statutory (i.e. whether it is an "invention" within the meaning of the UK equivalent to section 2 of the *Patent Act*); in *Hitachi* one asks whether the technical matter of the claim is unobvious, and presumes the non-technical matter to be obvious (i.e. one asks whether the statutory matter of the claim is unobvious under the EPC equivalent to section 28.3 of the *Patent Act*); in the present approach, one asks whether the claim includes statutory subject-matter that has been contributed. These approaches are all, fundamentally, concerned with determining whether the matter of the claim that is novel, unobvious and useful is also statutory. Although the perspective from which the analysis is performed differs, the end result should be consistent.

14. *Canadian Gypsum Co. Ltd. v. Gypsum, Lime & Alabastine, Canada, Ltd.* [1931] Ex.C.R. 180; *Shell Oil v. Commissioner of Patents* [(1982), 67 C.P.R. (2nd), 1 (S.C.C.)] at pages 10-11

15. Any defects of form or content must, of course, be addressed before the claim will be allowed.

16. Examiners need not examine non-statutory matter for novelty and obviousness. Consequently, where it has been determined that a claim does not include contributed statutory subject-matter, but does include a discrete non-statutory feature, the discrete non-statutory feature is viewed as the "invention" being asserted and is objected to under section 2 of the *Patent Act*. Such an objection is made even if it is clear from the application itself, the prior art, or statements made by the applicant that the discrete non-statutory feature in a claim has not been contributed.

17. *Schlumberger Canada Ltd. v. Commissioner of Patents* [(1981), 56 C.P.R. (2nd), 204 (F.C.A.)] at page 206

18. *Schlumberger* (supra at 17)

19. *Lawson v. Commissioner of Patents* [(1970), 62 C.P.R. (1st), 101 (Ex.Ct.)]

20. "claim date" meaning the earlier of the filing date or valid priority date.

21. Searches performed by Canadian examiners as part of CIPO's obligations as an International Searching Authority are governed by the requirements of the PCT, and are not covered by this section of the manual.

22. Subsection 30(1) applies where a final action was not issued, and 30(5) where the application is found allowable subsequent to a response to a final action.

23. This refers to a final fee paid by the authorized correspondent on an application that has been allowed.

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Chapter 14
Unity of Invention

14.01 Scope of this chapter

The Canadian *Patent Act* and *Patent Rules* are based in part on the simple premise of *one patent for one invention*.[1] The concept of unity of invention refers to the requirement that an application claim *one invention only*. This requirement serves, in part, to ensure that the fees paid by applicants are fairly assessed on a per invention basis.

Requiring that a patent relate to *one invention only* also provides a measure of clarity to the patent system, by constraining the scope of individual patents. A patent specification directed to a single invention is clearer and more readily understood than one that attempts to describe and define several.

The present chapter deals with the subject of unity of invention from two perspectives. First, the assessment by an examiner of whether or not, for the purposes of examination, an application claims more than one invention, and with the procedures for dealing with an application that does and second, the framework and requirements for the filing of a divisional application to protect an invention other than the invention to which the claims of its parent application are limited.[2] The term "parent" is used to refer to an application that describes more than one invention, and which served as the basis for the filing of a further application (a "divisional" application) to protect an invention other than the one ultimately claimed in the parent.

Note that throughout the chapter the term "invention" is used to refer to subject-matter that an applicant alleges to be an invention (an "alleged invention"). Where, when assessing unity of invention, an examiner identifies a plurality of inventions in a claim set, this should not be taken as a suggestion that all of the several inventions thus identified have been assessed for patentability.

14.02 Unity of invention

The basic framework that governs unity of invention is section 36 of the *Patent Act*, which provides that

> *(1) A patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.*

Unity of invention has been referred to as "essentially a procedural matter",[3] as it does not of itself give rise to issues of validity. Section 36 of the *Patent Act* also sets out provisions whereby the claims are to be limited to *one invention only* and any additional inventions described (or described and claimed, as the case may be) may be protected by the filing of separate and distinct applications therefor. Thus

> *(2) Where an application (the "original application") describes more than one invention, the applicant may limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.*

and

> *(2.1) Where an application (the "original application") describes and claims more than one invention, the applicant shall, on the direction of the Commissioner, limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.*

As discussed in the following sections, it is important to approach the concept of unity of invention bearing in mind its legal context and purpose, and not to confuse it with the determination of whether or not one invention is "the same" as another such as is done, for example, when assessing novelty or double patenting and during re-issue proceedings.

14.03 Meaning of "one invention only"

In interpreting section 36 of the *Patent Act*, the term "invention" in the expression "one invention only" is best understood as having a broad meaning. The broad interpretation of the meaning of the term "invention" in section 36 of the *Patent Act* is reflected in section 36 of the *Patent Rules*, which provides that

> *For the purposes of section 36 of the Act or of the Act as it read immediately before October 1, 1989, an application does not claim more than one invention if the subject-matters defined by the claims are so linked as to form a single general inventive concept.*

In interpreting the scope of section 36 of the *Patent Act*, the Courts have ascribed to the term "invention" a meaning different than that provided in section 2 of the *Patent Act*.[4] The Courts thus spoke of claims to matter in different categories of invention as being "aspects of a single invention". A similar, broad interpretation of the meaning of "invention" has been ascribed by the Courts in considering other provisions of the Act.[5] It is clear that the Courts have considered that the legislative intent of section 36 of the *Patent Act* is not fulfilled by interpreting the expression "one invention only" by giving the term "invention" its definition from section 2 of the *Patent Act*. That is, section 36 of the *Patent Act* should not be understood to say *where an application (the "original application") describes and claims more than one new and useful art, process, machine, manufacture or composition of matter [...], the applicant shall [...] limit the claims to one invention only [...].*

Thus, as directed by section 36 of the *Patent Rules*, an application will not be considered to claim more than one invention if the subject-matters defined by the claims are so linked as to form a single general inventive concept.

14.04 Canadian unity standard harmonious with PCT standard

The 1996 revision of the *Patent Act* and *Patent Rules* had as one of its objects the harmonization of the Canadian patent framework with the *Patent Cooperation Treaty* standards.[6]

This can be readily appreciated by comparing the language of section 36 of the *Patent Rules* with that of section 13.1 of the *Regulations Under the PCT*, which states that

> *The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").*

The phrase "one invention only" in section 36 of the *Patent Act*, when understood in its full context and in view of section 36 of the *Patent Rules* (as discussed in 14.03), has a meaning equivalent to "one invention only or to a group of inventions so linked as to form a single general inventive concept" in Rule 13.1 of the *Regulations Under the PCT*.

The result is that the Canadian unity of invention requirement is not "different from or additional to" that provided for in the *Patent Cooperation Treaty*. Identifying a defect arising from non-compliance with the requirements of section 36 of the *Patent Act* does not contravene article 27(1) of the *PCT*.[7]

14.05 General inventive concept

Assessing whether or not unity of invention exists in a given claim set amounts to determining, having regard to the specification as a whole, whether or not a "single general inventive concept" exists to link the claims.[8]

The inventive concept can be identified by considering the purpose of the invention.

The claimed invention should provide a solution to a practical problem, and claims that define that solution or refinements to that solution (or of how it is to be put into operation or manufactured, as the case may be) may all relate to a single inventive concept. Generally, a set of claims will share a general inventive concept if a set of new and unobvious elements is common to each claim in the set, provided the elements in question are those required for the proper operation of the invention in its broadest aspects.

The inventive concept relates to how a result is obtained (i.e. to the inventive aspects of a practical solution to a problem), and not simply to the idea of obtaining the result *per se*. The correct standard to consider is that of unity of invention (i.e. unity among the solutions to a problem), rather than "unity of result". Mutually unobvious means (practical forms) for achieving a given result will generally not share a single general inventive concept.

The PCT expresses the concept similarly, in Rule 13.2 of the *Regulations Under the PCT*, which states that

> *Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.*

The expression "special technical features" used in the PCT Regulations refers to novel and unobvious elements of the claims that are responsible for the proper operation of the invention.

14.06 *A priori* and *a posteriori* evaluation

Claims that have in common a set of new and unobvious elements [as described in 14.05] satisfy the requirement for unity of invention.

The two aspects of the unity of invention requirement can be considered separately as: 1) the need for a common set of elements among the claims, and 2) the requirement that the common set of elements be new and unobvious (*i.e.* inventive) over the prior art.

The former can be assessed without regard to the state of the art, and is referred to as an *a priori* evaluation of unity of invention, whereas the latter requires the state of the art to be considered and is referred to as an *a posteriori* evaluation. A lack of unity of invention is a defect in an application regardless of whether it is identified *a priori* or *a posteriori*.

A typical approach for assessing whether the claims have unity of invention is to identify the claim with the fewest elements, and then check to see if those same elements appear in all the other independent claims. The claims may appear to lack unity of invention *a priori* where no claim defines solely those elements that are common to all the claims, however the absence of such a claim is not determinative since there is no requirement that there be one claim broader than all others, nor that there be only one independent claim in each category of *invention* [see 14.08.02 for additional guidance on this point].

In assessing whether a common set of elements is present, the language of section 13.2 of the *Regulations Under the PCT* should be borne in mind - that the claims must include "the same or corresponding special technical features". The concept of "corresponding" means that two claims can have unity of invention even if they do not share a set of precisely identical elements, but rather share equivalent elements whose roles in the context of the invention correspond.[9]

Any prior art relevant for a determination of anticipation or obviousness under section 28.2 or 28.3 of the *Patent Act* may be considered in assessing whether unity of invention exists [see chapter 15 of this manual].

Example 1:

[This example sets forth an *a priori* analysis.]

An application discloses a paint containing a rust-inhibiting substance X, a process for applying said paint with substance X and an electrode arrangement A for applying paint. The electrode arrangement is useful for applying paint in general, and is not required in order to apply the paint comprising substance X (the benefits of having substance X in the paint are unrelated to how the paint is applied).[10]

Claims:

1. A paint comprising a rust-inhibiting substance X.

2. An apparatus for electrostatically charging atomized particles, comprising an arrangement of electrodes A.

3. An apparatus for electrostatically charging atomized particles, comprising an arrangement of electrodes A, wherein said apparatus is for applying the paint of claim 1.

4. A process for painting an article, said process comprising the steps of
i) atomizing the paint of claim 1 using compressed air;
ii) electrostatically charging the atomized paint using an electrode arrangement A; and
iii) directing the paint to the article.

Analysis: An *a priori* assessment of the claims reveals two alleged inventions: the paint comprising substance X and the apparatus including electrode arrangement A. The special technical feature of claim 1 is substance X. The special technical feature of claim 2 is electrode arrangement A. Substance X and electrode arrangement A do not cooperate in any way. Claim 4 includes the technical features of both claims 1 and 2. Claim 3 makes reference to the technical features of both claims 1 and 2, but it must be determined whether the reference to the paint of claim 1 implies a practical limitation to the structure of the apparatus. If the apparatus of claim 2 is suitable for painting the paint of claim 1 (as it seems to be, in view of claim 4), then claim 3 defines the same apparatus as claim 2 and would lack unity of invention with claim 1 despite the reference to that claim.

There is an *a priori* lack of unity between claims 1 and 2, since the two claims do not share a technical feature in common. Unity of invention does exist between claims 1 and 4 (on the basis of the paint comprising substance X) and between claims 2, 3 and 4 (on the basis of the electrode arrangement A).

Note that while claim 4 can be included in an application with either claim 1 or claim 2, if it was maintained in the parent and filed in a divisional application the result would be double-patenting. Therefore, the subject-matter of claim 4 may be included in the claims of the parent or of the divisional, but not both.

Example 2:

[This example sets forth an *a posteriori* analysis.]

The application describes a computer monitor comprising elements A and B, and further discloses that additional elements C and D lead, respectively, to particular advantages.

A search of the prior art reveals document D1, which discloses a computer monitor comprising elements A and B.

Claims:

1. A computer monitor comprising elements A and B.

2. A computer monitor according to claim 1, further comprising element C.

3. A computer monitor according to claim 1, further comprising element D.

Analysis: The claims meet the requirement for unity of invention on an *a priori* assessment, since elements A and B are common to each claim. In view of D1, however, these elements do not provide a general inventive concept that links the claims. To the extent that elements C and D have each been disclosed in the application as leading to particular, mutually unobvious advantages, claims 2 and 3 are directed to distinct inventions that lack unity of invention *a posteriori*.

If, on the other hand, it is clear to the examiner from the description and/or the prior art that features C and D do not provide inventive solutions to any practical problem facing the art (and are therefore not the result of further invention over the matter of claim 1), such that D1 renders claims 2 and 3 either anticipated or obvious, then only the consequent defects under sections 28.2 and/or 28.3 of the *Patent Act* should be identified. No defect under section 36 of the *Patent Act* should then be identified, although the examiner may note the potential lack of unity that might exist once the prior art defects are addressed [see 14.07.03].

14.07 Examining for unity of invention

The Office takes the position that the intent of subsection 36(1) of the *Patent Act* is that where an application describes and claims more than one invention, the claims require amendment so as to define *one invention only*. A lack of unity of invention among the claims is identified as non-compliance with subsection 36(1) of the *Patent Act* and the applicant is notified of the defect and requisitioned to correct it or to submit arguments as to why the claims do comply with section 36 of the *Patent Act*. This notification is made in an examiner's report issued under subsection 30(2) of the *Patent Rules*.

Given that, where a lack of unity of invention has been identified, the examiner cannot be certain which invention the applicant will elect to maintain in the claims, a report identifying non-compliance with section 36 of the *Patent Act* need only identify this defect. This is an exception to the usual requirement that a requisition under subsection 30(2) of the *Patent Rules* be based on a comprehensive examination [see section 13.05 of this manual]. In this sense, addressing a question of unity of invention can be viewed as a procedural matter to be resolved separately from the substantive examination of the application.

Where the applicant responds to a requisition identifying a lack of unity of invention by amending the claims in such a manner as to overcome the defect, this determines for that application the *one invention only* referred to in subsection 36(2) of the *Patent Act* [see 14.03]. Thereafter, *any other invention disclosed may be made the subject of a divisional application*. The Office takes the position that, in accordance with subsection 36(2) of the *Patent Act*, the claims of the original application [see 14.11] under examination may no longer be directed to the matter of *any other invention disclosed*. In responding to an examiner's report identifying a lack of unity of invention, the applicant effectively has the right to elect, one time only, the identity of the *one invention only* that will be the subject of examination in a given application.

Claims resulting from post-election amendments will generally be permissible in the application if they would have had unity of invention with the claims to the *one invention only* elected by the applicant.

To avoid prolonged debate over unity of invention, where an examiner considers that the claims lack unity of invention and the applicant declines to limit their claims to a single invention, the examiner may refer the application to the Commissioner of Patents for a determination of the issue. Typically, such a referral will not occur until the examiner has advised the applicant of the defect in at least two reports.

This referral will not take the form of a Final Action, since:

> (a) should the applicant limit the claims to *one invention only* in response to a Final Action, subsection 30(5) of the *Patent Rules* would require the examiner to withdraw the rejection; this should generally result in allowance of the application, but in the case of a lack of unity of invention the claims would generally not have been fully examined; and
>
> (b) should the Commissioner conclude after a review in accordance with subsection 30(6) of the *Patent Rules* that the application does not comply with subsection 36(1) of the *Patent Act*, no further amendment of the application would be possible in view of section 31 of the *Patent Rules*.

Where a review of the application [see 14.07.06] leads to the conclusion that the application complies with section 36 of the *Patent Act*, the examiner will resume prosecution and consider all the claims on file.

Where the Commissioner reviews the application and has reason to believe that it does not comply with section 36 of the *Patent Act*, a letter will be sent to the applicant directing that the claims be limited to *one invention only*. This direction will be made under authority of subsection 36(2.1) of the *Patent Act*, and is not a requisition under section 30 of the *Patent Rules*.

Where the applicant's amendments in response to the letter make the application compliant with section 36 of the *Patent Act*, examination of the application will continue. If the applicant's amendments in response to the letter fail to satisfy the Commissioner that the application complies with section 36 of the *Patent Act*, the application may be refused under section 40 of the *Patent Act*.

14.07.01 Content of the report

Whenever a report is written that identifies lack of unity of invention as a defect, an indication must be included in the report of the extent of the search and examination performed on the application as a whole.

As noted in 14.07, a report identifying a lack of unity may be limited in scope to address only that defect. This will usually be the case where a lack of unity is identified at the outset of prosecution. Where a lack of unity is identified later in prosecution, the facts of the case may be such that it is more efficient to identify this defect in parallel with a comprehensive examination of some or all of the claims, rather than interrupting the substantive examination in order to deal with the unity of invention defect alone.

Even where a lack of unity of invention is identified as a defect at the outset of prosecution, if the examiner believes (for example, in view of corresponding patents issued in other jurisdictions) they know which group of claims an applicant will elect for prosecution, they may include in their report an identification of all the defects associated with these claims. The choice of the examiner does not replace the applicant's right to make their one-time election [see 14.07]. If the applicant elects a different group of claims for prosecution from the one the examiner chose to examine, prosecution proceeds on the basis of the claims elected by the applicant.

Where there are defects in the application that affect the determination of unity of invention, an examiner may refer to these defects in addition to or instead of the lack of unity defect and should set out how the other defects impact the assessment of unity of invention or vice versa. Defects such as lack of clarity in the claims, or prior art that leads to a conclusion of *a posteriori* lack of unity of invention are illustrative of the types of additional defects whose resolution may impact the determination. To avoid confusion as to the necessary response by the applicant, it may be preferable to identify such defects informally (e.g. in the preamble of the report, or by otherwise explicitly indicating that the defect is not being formally identified), solely to explain the impact they had on assessing unity of invention.

14.07.02 Explaining a lack of unity defect

A report identifying a lack of unity of invention should explain the basis for the conclusion in a manner that will enable the applicant to decide whether and how to limit or divide their claims for further examination. This explanation should identify what the examiner considers the various distinct inventions to be, and should provide sufficient detail so that the applicant can understand why the different inventions do not share a single general inventive concept. Where the defect is identified *a posteriori*, the prior art supporting this conclusion should be cited in the report and an explanation of the significance of each document should be provided.

Wherever possible, the individual inventions identified should be related to the claims in which they are defined, so that the applicant can group their claims into sets which would be viewed by the Office as sharing a single general inventive concept. This will generally be done in all cases unless attempting to relate each invention to a specific claim or claims would only introduce a lack of clarity into the explanation of the defect. Other than in exceptional cases, the examiner will set out groups of claims that are considered to be directed to *one invention only*. When creating such groups, the examiner should clearly indicate to which group each independent claim belongs. Unless an explicit indication has been made by the examiner with respect to a given dependent claim, the applicant may presume that a dependent claim belongs to the group in which the claim it refers to is found.

Where a lack of unity exists among the alternatives defined in a single claim, the examiner will, to the extent practical, separate the various inventions into groups. In such a case, unless otherwise indicated by the examiner, a dependent claim belongs to the group in which the alternative it refers to is found.

As a general rule, if the applicant limits the claims in the application to one group of claims identified by the examiner, the application will be considered to have been made compliant with section 36 of the *Patent Act*. Certain exceptions to this general rule exist, however, such as where a further lack of unity of invention subsequently becomes apparent in view of prior art discovered after the applicant has elected a group of claims for prosecution.

Note that in identifying the various inventions in a claim set, the term "invention" is used as a matter of convenience only, and in no way implies that the subject-matter of any given claim is patentable.

14.07.03 When a lack of unity defect can be identified

In general, a lack of unity of invention should be identified in the first report written in respect of the claims that lack unity of invention.

In some cases, an examiner may identify defects in an application that bear on the question of whether the claims have unity of invention (e.g. obviousness, ambiguity, lack of utility or of support). Where the applicant's response in respect of the other defects is germane to its evaluation, it is permissible for the lack of unity of invention defect to be formally identified in a later report. Whenever possible, the applicant should be advised that the other defects bear on the question of unity of invention.

Since unity of invention is assessed in view of the claims of the application, a lack of unity of invention may be introduced when amendments are made to the claims. Where a lack of unity of invention is introduced by the applicant with an amendment, an examiner may identify the resultant defect regardless of the length of prior examination of the application.

Where prior art raises the possibility of *a posteriori* lack of unity, but some of the claims in the application are considered by the examiner to be anticipated or obvious in view of the cited prior art, it may be preferable to not identify the lack of unity of invention as a formal defect until the prior art defect has been addressed by the applicant. The applicant's response to the prior art defect may advance the examiner's understanding regarding unity of invention. The examiner may draw the applicant's attention, informally [see 14.07.01] and depending on the circumstances, to the potential unity defect.

If the applicant responds to a prior art objection by amending the claims, and the claims as amended appear to avoid the cited prior art but to lack unity of invention, an examiner may identify the lack of unity defect.

14.07.04 Responding to a requisition

As with any requisition sent under subsection 30(2) of the *Patent Rules*, an applicant may respond to the identification of a lack of unity of invention by amending the application (in order to comply with subsection 36(1) of the *Patent Act*) or by submitting arguments as to why the application already does comply.

Where the applicant amends the claims by limiting them to claims falling within a single group identified by the examiner, the lack of unity defect identified in the issued report will be considered to have been overcome in respect of those claims [see 14.07.02].

Should the applicant agree that there is a lack of unity of invention among the claims, but disagree as to the grouping of claims set out by the examiner, they may respond to the requisition by identifying groups of claims different from those identified by the examiner and electing one of those groups of claims.

Where the applicant's response to the requisition does not serve to make the claims compliant with the requirement for unity of invention, a further report identifying the lack of unity defect may be sent.

14.07.05 Election of an invention

The applicant will be considered to have elected an invention whenever, subsequent to a report in which a lack of unity of invention was identified as a defect, the applicant limits the claims to fewer inventions than were defined in the claim set with respect to which the lack of unity of invention was identified. It is not necessary for the applicant to explicitly state that they have "elected the invention of Group A" when making an election (although this may certainly be done by the applicant, in the interest of greater clarity).

Where the applicant's initial election limits the claims to a single invention, this defines the *one invention only* referred to in subsection 36(2) of the *Patent Act* [see 14.07].

Where the applicant initially elects more than one group of claims identified by the examiner, or claims belonging to more than one group of claims identified by the examiner, or even submits new claims entirely, any further election that may be necessary (i.e. should the initially elected claims still lack unity of invention) must be made from among the inventions defined in the initially elected claim set.

14.07.06 Referral to the Commissioner of Patents

As noted in 14.07, where an examiner considers that the claims lack unity of invention and has notified the applicant of this conclusion, but the applicant declines to limit their claims to a single invention, the application may be forwarded to the Commissioner of Patents for a determination of the issue.

Resolving questions of unity of invention should be conducted efficiently, since the substantive examination of the application is delayed by this procedure. Consequently, if an applicant has been notified of a lack of unity of invention defect in at least two reports they should expect that a referral to the Commissioner could be made without further notification.

To ensure consistency and fairness, where an examiner considers that an application should be referred to the Commissioner, they must first submit the application for review by a Unity Review Board (URB). This board will review the application in order to ensure the lack of unity defect was correctly identified and clearly articulated to the applicant, so that the applicant was in a position to successfully respond to the examiner's requisition.

Where the URB considers that unity of invention exists, the examiner will proceed with the substantive examination of all claims on file.

Where the URB considers that a lack of unity of invention exists, but that further clarification of the matter is necessary (e.g., further reasons for concluding a defect exists, or additional information regarding the identity of acceptable claim groups), the examiner will issue a further report taking into account the observations of the URB.

Where the URB considers that a lack of unity of invention exists, and has been clearly communicated to the applicant in an examiner's report such that the applicant could have responded successfully to the examiner's requisition, the application will be forwarded to the Commissioner of Patents for consideration.

Where the Commissioner considers it appropriate, the applicant will be directed to limit the claims under authority of subsection 36(2.1) of the *Patent Act*. A Notice of Direction will then be sent to the applicant by the Commissioner.

Where the applicant's response to the Notice of Direction does not satisfy the examiner that the application complies with section 36 of the *Patent Act*, the application will be forwarded to the Patent Appeal Board for a final review. At this stage, the process resembles the review of a Final Action [see chapter 21 of this manual], given that the Patent Appeal Board may recommend that the Commissioner refuse the application under section 40 of the *Patent Act*. In accordance with subsection 30(6) of the *Patent Rules*, an application will not be refused without the applicant being given an opportunity to be heard.

14.08 Specific guidance

The following sections provide more specific guidance on assessing unity of invention.

14.08.01 Claims in different categories of *invention*

In general, it can be presumed when assessing unity of invention *a priori* that claims in the following categories of invention will satisfy the requirements of section 36 of the *Patent Rules* when present in a single application:

(*a*) a product and a process for making that product;
(*b*) a product and a use (or method of using) that product;
(*c*) a product, a process for making that product, and a use of that product;
(*d*) an apparatus and a process carried out on that apparatus.

Where the "process for making a product" of (*a*) or (*c*) is a "process carried out on an apparatus" within the meaning of (*d*), claims to the apparatus can be included in a single application with claims to the product, process for making the product and use of the product so long as the product is inventive by reason of properties that arise by virtue of its being prepared using the apparatus.

Note that it is not required that the scope of the claims to subject-matter in different categories of invention be of similar breadth in order to satisfy the requirement of unity of invention. Where the scopes are equivalent, unity will generally exist *a priori*. Where the scopes are different, unity may still exist.

For example, a broad process for using products could have unity of invention with a narrow product claim defining only a limited number of the products used in that process (see Example 2, below).

Example 1:

An application discloses a fuel burner wherein the use of inlets arranged tangentially to the mixing chamber results in better mixing and more efficient combustion.[11]

Claims:

1. A fuel burner comprising tangential fuel inlets into a mixing chamber.

2 A process for making a fuel burner, comprising the step of forming tangential fuel inlets into a mixing chamber.

3. A process for making a fuel burner comprising casting step A.

4. An apparatus for carrying out a process for making a fuel burner, comprising feature X which causes the formation of tangential fuel inlets.

5. An apparatus for carrying out a process for making a fuel burner comprising a protective housing B.

6. A process of manufacturing carbon black, comprising the step of tangentially introducing fuel into a mixing chamber of a fuel burner.

Analysis: Unity of invention exists, *a priori*, among claims 1, 2, 4, and 6. The special technical feature apparently common to these claims is the tangential fuel inlets. Claims 3 and 5 lack this feature, or a corresponding feature [see 14.06], and therefore lack unity of invention both with respect to each other and to the remaining claims. A lack of unity of invention might be identified *a posteriori* once a search of the prior art had been performed.

Example 2:

An application discloses the discovery that certain compounds, some novel and others known, are useful as plant growth regulants. The compounds are disclosed as a genus (a family of molecules) of common formula A, which comprises specific molecules a_1, a_2, a_3, ..., a_n. Compounds belonging to the sub-genus A' are disclosed as being novel, and a_1 is taught as a particularly preferred embodiment. No prior art is cited against the novelty of the compositions of claim 1.

Claims:

1. A plant growth regulant composition comprising a compound of formula A and a carrier.

2. A process for regulating plant growth comprising the step of applying a plant growth regulant composition of claim 1 to a plant.

3. A compound of formula A'.

4. Compound a_1.

Analysis: The claims all define compounds that share a common structure that is responsible for their plant-growth regulant properties. The discovery that this structure results in plant-growth regulant properties (i.e. the allegedly new use of compounds A) appears to be the single general inventive concept linking the claims. There is *a priori* unity of invention among claims 1 to 4.

14.08.02 Unity without a claim to the inventive linking feature

Since unity of invention is initially assessed *a priori* in view of the claims and before the prior art is considered, a lack of unity of invention may be identified in a report where the subject-matter of the claims does not appear to share a single general inventive concept.

As noted in 14.05, a single general inventive concept is identified by finding common elements among the various claims. This is generally done by identifying the claim with the fewest elements, and then checking to see if those same elements appear in all the other independent claims. The claims may appear to lack unity of invention *a priori* where no claim defines solely those elements that are common to all the claims.

An applicant is not required to claim the entire scope of their invention, however, so a claim defining only the common elements is not required in order to provide a linking inventive concept. In performing an *a priori* assessment of unity of invention, an examiner must consider the teachings of the description and the common general knowledge in the art before concluding that the claims clearly lack a single general inventive concept. If it is clear that the description discloses a particular set of elements that are common to all the claims as being the general inventive concept, unity of invention *a priori* should be acknowledged.

Where an examiner identifies a lack of unity of invention *a priori*, an applicant may respond to a report identifying this defect by identifying those features which they consider to be the inventive elements common to all their claims. The examiner may subsequently verify this assertion by performing a search on the basis of those elements.

Example 1:

The application as filed discloses a class of compounds of formula X wherein all members of X are aliphatic organothiophosphates, methods for preparing compounds of formula X and uses of compounds of formula X as insecticides. The description does not suggest that the class of compounds forms part of the invention.

Claims:

1. A method of preparing a compound of formula X by combining a compound of formula A with a compound of formula B.

2. The use of a compound of formula X as an insecticide.

Analysis: An *a priori* assessment of unity of invention presumes the features defined in the claims are those necessary to render the claims novel and inventive. Independent claims 1 and 2 have compounds of formula X in common, but since such compounds have not been claimed it will be presumed (in view of the description) that they are not an invention in and of themselves. The claims therefore appear to lack unity of invention on an *a priori* basis. Note that no presumption exists that claims to a "method of preparing X" and to a "use of X" share unity of invention [see 14.08.01 for the combinations of claims for which a presumption of unity of invention exists].

If the applicant considers that the class of compounds of formula X are, in fact, novel and inventive, they could respond to a report identifying the apparent lack of unity of invention by asserting that fact. A search of the prior art on the compounds of formula X would validate this assertion. If such a search failed to disclose any relevant prior art, no further searching in respect of the claims would be necessary. If the search identified relevant prior art, the claims would lack unity of invention *a posteriori*.

Example 2:

The application as filed discloses that a class of known compounds of formula X, wherein all members of X are 3,4-substituted indoles, are 5HT receptor antagonists and are useful as migraine therapeutics and anti-depressants. The usefulness of 5HT receptor antagonists in treating both migraine and depression is known in the art, but the 5HT-antagonist activity of compounds of formula X had not previously been identified.

Claims:

1. The use of a compound of formula X as a migraine therapeutic.

2. The use of a compound of formula X as an anti-depressant.

Analysis: The general inventive concept resident in both claims is the discovery that the compounds of formula X are 5HT receptor antagonists. Although this feature is not explicitly defined in each claim, it is understood in view of the description to be the basis of the invention. When read in light of the description, the claims have unity of invention *a priori*.

14.08.03 Unity of invention and utility

An invention is something that is, *inter alia*, new, inventive and useful. The utility of claimed subject-matter can be indicative of whether one is dealing with a single invention or multiple inventions.

An applicant must establish the utility of their invention by either demonstration or sound prediction [see section 12.08.03 of this manual]. In cases where utility is being established by sound prediction, the nature of the prediction can inform the unity of invention inquiry. Where the claims include many embodiments, and the utility of all of these could be soundly predicted using a single line of reasoning founded on a single set of facts, it is likely that unity of invention exists among the claims. In contrast, if different parts of the claimed matter would require significantly different sound predictions to support their utility, it is likely that the claims include multiple inventions and that there is a lack of unity of invention.[12]

Where different embodiments within a given category of invention are claimed (e.g. species within an inventive genus), and the embodiments all share a generic utility, they may be viewed as aspects of a single invention. Where one embodiment has a significantly different utility than the others, it may also be viewed as a different invention.

Consider a drug of generic formula X for treating asthma and a species A within the genus, where A has significantly different utility from a typical drug X. If the substantially different utility exists in addition to the generic utility, the embodiment can be viewed both as an aspect of a single, larger invention and as a separate invention. Such a circumstance arises, for example, in the case of inventions with different levels of preferred embodiments and unity of invention would typically exist in such a case. Consider that species A treats asthma, but without a side-effect common to drug X in general. Species A is an inventive selection from drug X, and could either be claimed in a separate application or in the same application as the genus X.

If the substantially different utility exists in place of the generic utility, however, the one embodiment does not have the same utility as the other embodiments and is, by consequence, a different invention. Unity of invention would typically not exist in such a case. Here, species A turns out to be a very good decongestant but is not useful in treating asthma. It does not share unity of invention with the genus X.[13]

14.08.04 Markush groups and lists of alternatives

A Markush group must define a list of alternatives that, for the purposes of the claimed invention, can be viewed as technical equivalents that perform the same function in substantially the same way. The person skilled in the art should expect that one member of a Markush group is directly substitutable for another in operable embodiments of the invention. A Markush group is identified by the form "an [alternative] selected from the group consisting of [a_1, a_2, a_3, a_{n-1}], and [a_n]".

Markush groups are most common in the chemical arts; a group of chemical compounds may be appropriately defined in a Markush group if each alternative has a common property or activity and either

- (*a*) shares a common structure with all other alternatives, wherein the shared structure is relevant to the activity of the alternatives in the invention; or
- (*b*) belongs to a class of compounds recognised in the art to which the invention pertains and all members of the group would be expected to behave the same way in the context of the invention.

Where the alternatives defined in a Markush group do not satisfy the requirements of (*b*), and where unity of invention cannot be established by elements in the claim other than the Markush group, either the shared structure referred to in (*a*) or its utility in the context of the invention would need to be novel and inventive over the prior art in order to provide unity of invention to the claimed alternatives.

Where a list of alternatives satisfies the requirements set out above, unity of invention will generally be acknowledged whether the alternatives are claimed in the form of a Markush group or not.[14]

14.08.05 Intermediates and final products

An intermediate that is physically or chemically transformed to produce a final product may be considered to have unity of invention with the final product, despite that the inventive step and utility that support the patentability of the intermediate and final product may be quite distinct from each other.

The intermediate must, necessarily, be useful for producing the final product. It may also have the same utility as the final product, although this is not required.

To have unity of invention with the final product, the intermediate should share with the final product the principal structural elements of the final product or should serve to introduce to the final product a structural element that is essential to its utility. Different intermediates that introduce different structural parts to the final product, however, will generally not be considered to share unity of invention amongst each other.[15]

Furthermore, the intermediate must be a direct precursor to the final product, in the sense of being removed from the final product by only one or a few steps, and must not be a precursor to a subsequent intermediate that is known in the art and that must be produced on the way to the final product.[16]

The concept of "intermediates and final products" is common in chemical synthesis, but could apply in other arts as well.

Chemical examples of intermediates and final products that could be considered to have unity of invention include:

(i) a biologically inactive compound (the intermediate) that is deprotected to produce an active drug (the final product). The deprotection renders the final product active, but the overall structure of the intermediate and the final product are otherwise almost equivalent;

(ii) an intermediate in a multi-step synthesis that contains a structure which, upon ring-closing, produces a critical functionality in a final product, where the final product is prepared by reacting the intermediate with a polycyclic aromatic compound and subsequently ring-closing the structure introduced by the intermediate. The intermediate and the final product have very different structures, since the intermediate does not include the polycyclic scaffold of the final product. Nevertheless, the critical element of the final product results directly from the intermediate, and there are no known intermediates produced in the synthetic steps leading from the claimed intermediate to the final product.

Example 1:

An application discloses an industrially useful triazole compound defined by formula I, and a method for its preparation by ring-closure of a compound of formula II. The critical structure in the triazole product is the combination of the triazole ring (sub-structure A) with proximal substituted aromatic rings (structures B and D). The necessary stereochemistry of the groups A, B and D is provided by a central ring structure C. The description teaches that the ring structure C can be formed by a ring-closing reaction of functional groups E and F, which are present in the immediate precursor to the final product. The only disclosed utility of the intermediate is in the production of the final product.

Claims:

1. A compound of formula I comprising sub-structures A-B-C-D.

2. A compound of formula II comprising sub-structures A-B-E-F-D.

Analysis: Although the core structures of compound I (final product) and compound II (intermediate) differ considerably, compound II is an open-ring precursor to compound I. Both compounds share principal structural elements, namely the triazole A and the substituted aromatic rings B and D. The intermediate structure E-F is, from a chemical perspective, a known precursor for rings of type C. The two structures are, overall, technically closely interrelated and unity of invention exists.[17]

Example 2:

An application discloses two structurally related molecules A and B. Molecule A is a compound with analgesic properties. Molecule B results from selective methylation and acylation of two hydroxy groups on A. Compound B is not an effective analgesic, but has significant bioactivity as a sedative.

Claims:

1. A compound of structure A.

2. A compound of structure B.

3. A method for converting compound A into compound B through sequential selective methylation and acylation, comprising the steps [...].

4. A use of A as an analgesic.

5. A use of B as a sedative.

Analysis: Compound A is an intermediate that is structurally similar to compound B. Claims 1 and 2 share unity of invention, and share unity of invention with claim 3.

Claim 5 defines the use of compound B, and shares unity of invention with claims 2 and 3 (a product, process to produce the product and use of the product - see 14.08.01). Although claim 5 does not clearly share unity of invention with claim 1, claims 1, 2, 3 and 5 would typically be considered to have unity of invention in a single application (intermediate to produce B, compound B, process to produce B, and use of B).

Claim 4 lacks unity of invention with claims 2, 3 and 5 as it defines a use of intermediate A other than its use in preparing the final product or an equivalent use to the product's. Claim 4 (use of A) does share unity of invention with claim 1 (intermediate A). If desired, claim 3 could be included in an application with claims 1 and 4 (considering claim 3 to be a use of A), although in practice it would usually be preferable to include claim 3 in the same application as claims 2 and 5 (considering claim 3 to be a process to produce B).[18] Claim 4 could be claimed in a divisional application.

14.08.06 Multi-step methods of preparation

Some preparative methods will include more than one step that could be patentable independently of the multi-step preparative method as a whole. This applies particularly to multi-step synthetic methods, although in principle the concepts could apply to any multi-step preparative method (e.g. a method of manufacturing).

For the purposes of unity of invention, an application can include a claim to a single inventive transformative step in a method and to any larger method involving that step up to the entire multi-step method. The utility of the transformative step arises from it transforming a precursor (which will be a starting material or intermediate in the overall method) into a product (which may be a further intermediate in the method or its final product). The transformative step will also typically share unity of invention with its product, and may share unity of invention with certain of the product's precursors (see 14.08.05).

Other individual steps in the method (or combinations of steps that do not include the inventive transformative step), however, will not have unity of invention with the inventive transformative step. The other step or combinations of steps do not share the general inventive concept of transforming the inventive transformative step's precursor into its product. Products other than those meeting the "intermediate and final product" requirements set out in 14.08.05 will likewise be considered not to share unity of invention with the inventive transformative step and its product.

Consider a multi-step synthesis involving the following steps:

step A transforming 1 into 2;
step B transforming 2 into 3;
step C transforming 3 into 4;
step D transforming 4 into 5; and
step E transforming 5 into 6.

The applicant considers steps A and D to be inventive, as well as the 5-step method as a whole. Starting material 1 and intermediates 3 and 4 are known, while intermediates 2 and 5 and final product 6 are novel.

The application includes claims to step D, to step E, and to intermediate 5 and the closely structurally-related final product 6. Unity of invention can be acknowledged among these claims as involving inventive product 5, a method for producing product 5 (step D), a method of using product 5 (step E) and by virtue of the "intermediate / final product" relationship between products 5 and 6 [see 14.08.05]. Unity of invention could not be acknowledged between intermediate 5 and intermediate 2 because of the intervening known intermediates 3 and 4 [see 14.08.05], nor could individual steps A, B

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or C be claimed either alone or in any combination other than one ending with step D (i.e. so that the combination could be viewed as a method for producing 5).

It is worth noting that other groups of claims could be identified which would meet the requirement for unity of invention. For example, a claim to the 5-step method as a whole would have unity with a claim to product 6, to intermediate 5 and to any combination of steps that includes step E on the basis of the general inventive concept being "the preparation of 6 from 5".

14.08.07 Unity and provisos

A proviso is a clause added to a claim in order to remove something that would otherwise be encompassed by the language of the claim.

A proviso may be used, for example, to provide or restore novelty in cases where some part of the claimed subject-matter would otherwise be anticipated.

Whether a proviso causes a lack of unity of invention must be assessed on the facts of a given case. A proviso can be thought of as making the subject-matter of the claim "discontinuous", and in that sense can remove the generality of what would otherwise be a "general inventive concept".

In assessing whether a proviso will have the effect of removing unity of invention from the claimed subject-matter, the reason for including the proviso must be considered. Where a proviso is used to avoid prior art, for example, the critical question is whether the prior art has simply disclosed an embodiment falling within a claim or has taught the same inventive concept as the application. In the latter case, unity of invention is most likely absent in view of the proviso whereas in the former this may not be the case.

Example:

An application discloses a genus of compounds (compounds comprising the structure of formula I) useful as antibiotics. The inventors have discovered and disclosed a structure-function relationship based on a certain functional group in the genus. The same applicants had, several years earlier, obtained a patent on a species (species A) falling within the genus. At the time the previous patent was obtained, the applicants knew the species was a useful antibiotic but did not know what structure led to the activity.

Claims:

1. A compound comprising the structure defined by formula I, provided that said compound is not "species A".

2. A compound according to claim 1, wherein said compound is species B.

3. A compound according to claim 1, wherein said compound is species C.

4. A compound according to claim 1, wherein said compound is species D.

Analysis: The general inventive concept linking the compounds of formula I is the presence of the functional group responsible for their antibiotic activity, coupled with the discovery of the structure-function relationship. The prior patent had not disclosed the structure-function relationship, and although species A would anticipate the broad genus claim in the absence of the proviso, the proviso does not result in a lack of unity of invention among the remaining members of the genus.

Note that if the earlier patent had identified the structure-function relationship in respect of species A, it would imply a lack of unity of invention *a posteriori* since the role of the functional group in providing antibiotic activity would have been known.

14.08.08 Additional examples

As noted in 14.04, the Canadian standard for unity of invention is equivalent to that under the *Patent Cooperation Treaty.*

Additional examples helpful for understanding unity of invention can be found in sections 10.20 to 10.59 of the *PCT International Search and Preliminary Examination Guidelines*, available on the web site of the *World Intellectual Property Organization*.[19]

14.09 Right to file a divisional application

In accordance with subsections 36(2) and 36(2.1) of the *Patent Act*, where an application (the “original application”) describes more than one invention, an applicant may file a divisional application to protect described inventions other than the *one invention only* to which the original application’s claims were directed or, as the case may be, to which the original application’s claims were limited.

In accordance with subsections 36(2), 36(2.1) and 36(3) of the *Patent Act*, a divisional application must be filed before the original application either grants to patent or, where the original application has been abandoned, the period to reinstate it expires.

Only an applicant may file a divisional application, and only within the time period provided by statute. Although the term “applicant” is defined in section 2 of the *Patent Act* as including “an inventor and the legal representatives of an applicant or inventor”, the Office takes the position that only the current owner of the application can divide it by filing a divisional application.

14.10 Filing requirements for a divisional application

The filing of a divisional application is largely equivalent to the filing of an original application [see Chapter 5 of this manual].

When preparing the Petition (Form 3 of Schedule I of the *Patent Rules*), section 2 is completed. The Office considers any assignment registered in respect of the original application to also be registered in respect of the divisional application. In addition, any priority requested in respect of the original application will be considered to have been requested in respect of the divisional application unless the applicant advises the Office in writing that one or more priority claims are not to be considered.[20]

In accordance with subsection 36(4) of the *Patent Act*,[21] a divisional application is considered to be filed on the same date as the original application. In accordance with subsection 99(2) of the *Patent Rules*, any maintenance fee set out in item 30 of Schedule II of the *Patent Rules* that would have been payable pursuant to subsection 27.1(1) of the *Patent Act* had the divisional application been filed on the filing date of the original application shall be paid when the divisional application is actually filed.

In accordance with subsection 96(2) of the *Patent Rules*, a request for examination of a divisional application shall be made and the fee shall be paid before the later of the five-year period after the filing date of the original application and the six-month period after the date on which the divisional application is actually filed.

The Office takes the position that the applicable fee for requesting examination of a divisional application is that set out in item 3(b) of Schedule II. This is so irrespective of whether or not the original application resulted from the national phase entry of an international application that was the subject of an international search by the Commissioner.[22]

14.11 Meaning of "original application"

In accordance with subsection 36(4) of the *Patent Act*, a divisional application shall be deemed to be a separate and distinct application under the Act, to which the Act's provisions apply as fully as may be.

The Office takes the position that a divisional application may itself be considered an original application under section 36 of the *Patent Act* for the purposes of the filing of further divisional applications.

Thus, if a first application (the "grandparent" application) leads to a first divisional application (the "parent" application), a further divisional application (the "child" application) may be filed on the basis of either the parent application or the grandparent application.

The Office takes the position that in order for a divisional to be filed, section 36 of the Patent Act requires that either the parent or grandparent be eligible as an "original application", but not both. If, for example, the grandparent issued to patent or became abandoned and the period to reinstate expired, the parent application could be used to file a divisional in accordance with subsections 36(2), 36(2.1) and 36(3) of the *Patent Act*. This allows the provisions of these subsections to apply "as fully as may be" to the parent application, as provided for in subsection 36(4) of the *Patent Act*.

14.12 Time limits

In accordance with subsection 36(4) of the *Patent Act*, a divisional application shall have the same filing date as the original application.

Unless otherwise provided for in the Act or Rules, any time limit that would apply to a regularly filed application applies to a divisional application.

Where a divisional application is filed after the expiry of the 18 month confidentiality period specified in section 10 of the *Patent Act*, the application and any documents filed in connection with it shall be open to public inspection immediately upon filing. Note that the confidentiality period of a divisional application is calculated based on the earliest filing date of any previously filed application on which a request for priority is made in respect of the divisional application. A divisional application may not have all the priority claim dates that the original application from which it was divided has.

14.13 Examination of divisional applications

Where a request for examination has been made on a divisional application, examination will include a determination of whether the application is entitled to divisional status. The content of the specification and drawings of the purported divisional application are compared to that of the original application to determine if the claims of the divisional application are directed to a different invention than the claims of the parent, and if the divisional application contains any subject-matter that would have contravened subsection 38.2(2) or 38.2(3) of the *Patent Act* had it been added to the original application's specification or drawings by way of amendment.

Subsections 38.2(2) and 38.2(3) of the *Patent Act* provide that the specification and drawings, respectively, may not be amended to describe matter not reasonably to be inferred from the specification or drawings as originally filed ("new matter"). If the specification or drawings of a purported divisional application contain new matter with respect to the specification or drawings of the original application, the later filed application is not entirely based on the specification and drawings of the original application and is not entitled to divisional status. Simply put, something cannot be divided out of an application that could not legitimately have formed part of that application.

Similarly, if the claims in the purported divisional application are not directed to a different invention than those of the original application, the later-filed application is not a divisional application within the meaning of section 36 of the *Patent Act*.

A divisional application will be examined in its regular order according to the date on which the parent application's request for examination was made.

If, during examination, the later-filed application is considered to be not entitled to divisional status, the applicant will be notified of this conclusion and of the examiner's reasons for so concluding. Examination will proceed on the presumption that the application's filing date is the date on which the documents were actually submitted to the Office. Note that for practical reasons,[23] the electronic records of the Office will not be updated in view of this presumption unless the applicant subsequently agrees that the application is not a divisional application. An applicant may also respond to a requisition identifying the application as not entitled to divisional status by amending the application so that it becomes entitled to divisional status, or by providing arguments sufficient to convince the examiner that it is already entitled to that status.

Although the filing of an improper divisional is not, of itself, a defect in the application,[24] statements in the description asserting that the application is a divisional application will be considered inaccurate and be identified as defects under subsection 27(3) of the *Patent Act*.

Depending on the facts of the case, the purported "original application" may also be relevant prior art against the later application in the evaluation of novelty, obviousness or double-patenting. Note that if the filing of a divisional application was "directed by the Patent Office", the doctrine of double-patenting does not apply between the divisional and any of its parent or sibling applications.[25]

Endnotes for chapter 14

1. *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at page 168 referring to "the well-known rule that only one patent may issue for a given invention"; and *Teva Canada Ltd. v. Pfizer Canada Inc.* 2012 S.C.C. 60 at paragraph 58 affirming that "a patent shall be granted for one invention only."

2. Or of a divisional application to cover several additional inventions disclosed in the parent application, or of one or several divisional applications each to cover one of several additional inventions disclosed in the parent application.

3. *Merck & Co., Inc. v. Apotex Inc.* 2006 FC 524 at paragraph 203. Hughes J. also noted at paragraph 197 that "[d]uring the pendency of an application or several applications, the procedures to be followed are the prerogative of the Patent Office".

4. *Libby-Owens-Ford Glass Co. v. Ford Motor Co.* [(1970), 62 C.P.R. (1st), 223 (S.C.C.)] at pages 230-231, *Ciba-Geigy AG v. Commissioner of Patents* [(1982), 65 C.P.R. (2nd), 73 (F.C.A.)] at page 79

5. *Sociéte des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd.* [1966] Ex. C.R. 59 at paragraphs 6-8

6. In view of this, some content in this chapter mirrors or has been adapted from text found in the *PCT International Search and Preliminary Examination Guidelines* published by the *World Intellectual Property Office* (Geneva, 2011).

7. Article 27(1) *PCT* states: No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

8. *Teva* (supra at 1) at paragraph 64

9. For an example of corresponding elements, see section 10.29 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6).

10. This example is adapted from the example provided in section 10.23 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6).

11. This example is adapted from the example provided in section 10.26 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6).

12. The conclusion reached in section 10.43 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) can be understood in this light, presuming that a single line of reasoning cannot soundly predict why the various classes of herbicide B work with A to achieve the inventive result.

13. See also the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) at 10.42.

14. The conclusion reached in section 10.58 of the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) can be understood in this light, since compounds X, Y and Z do not share a structural feature responsible for their activity. It must be presumed that X, Y and Z are not members of a recognised class of compounds.

15. Due regard should be given to the nature of the synthesis in performing this evaluation. The relationship of the structure of an intermediate to the final product will be quite different in, for example, a convergent synthesis than in a divergent synthesis, or in a ring-closing or rearrangement reaction than in an addition reaction. See also the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) at 10.18(f).

16. See the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) at 10.18(e).

17. This example is loosely based on the *PCT International Search and Preliminary Examination Guidelines* (supra at 6) at 10.47, which provides specific chemical structures to illustrate the same point.

18. A method for preparing a product would usually be considered to render the product it produces obvious, and there could consequently be an appearance of double-patenting if claims 2 and 3 appeared in different applications.

19. *PCT International Search and Preliminary Examination Guidelines* (supra at 6).

20. Note that where the applicant has made a request in section 4 of the Petition for fewer priority documents than requested for the original application, only those priority claims requested in section 4 will be considered to have been made in respect of the divisional application.

21. An equivalent provision exists for applications filed prior to October 1, 1989, under subsection 36(4) of the *Patent Act* as it read immediately before that date.

22. This interpretation is consistent with the provisions of subsection 36(4) of the *Patent Act* and of subsection 58(10) of the *Patent Rules* (which provides that an

international application can only become one national phase application).

23. Many time periods are calculated from the assigned filing date. Prematurely changing the electronic records of the Office may result in confusion and potential risks to the applicant.

24. *Merck* (supra at 3) at paragraph 203

25. *Consolboard* (supra at 1) at page 169

Chapter 15
Requirements for patentability

15.01 Introduction

The subject matter protected by a patent is defined by the claims. This chapter deals with the various requirements imposed by law and jurisprudence on claims before they can be said to be directed to novel and unobvious subject matter in accordance with sections 28.2 and 28.3 of the *Patent Act*.

15.01.01 Novelty and anticipation

To be considered novel the whole of subject matter defined by a claim shall not form part of the state of the art. With respect to each claim in an application for patent in Canada the state of the art may be defined generally as everything disclosed in such a manner that it became available to the public in Canada or elsewhere before the **CLAIM DATE**. The **CLAIM DATE** of a claim in a Canadian patent application is the filing date of the application in Canada, unless, priority is claimed on an earlier filed application in Canada or elsewhere. In the latter case, the claim date is the filing date of the earliest application which supports the subject matter of the claim (Sections 2 and 28.1 of the *Patent Act*).

If the subject matter defined by a claim in an application is disclosed completely in a single prior art reference, it is considered to be anticipated by the reference (meaning lacking in novelty). In this situation the examiner will inform the applicant of the defect and requisition the applicant to amend the application to comply with the *Patent Act* and Rules or to provide arguments as to why the application does comply. The defect in this case is that the claim lacks novelty in view of the prior art (i.e. is anticipated by the reference). Although novelty is assessed on the basis of a single item of prior art, it is permitted to read into prior art things that can be considered to be implicit therein, but references may not be combined to find a lack of novelty. Combining references to show lack of novelty has been referred to as an improper "mosaic" of references (Pope v. Spanish River 46 RPC 1929).

15.01.02 Obviousness

A claim will be objected to under section 28.3 of the *Patent Act* if it is considered to be obvious to one of skill in the art or science, on the claim date. The test for obviousness is essentially whether or not an unimaginative skilled technician would, in the light of the state of the art and common general knowledge at the claim date, be led directly and without difficulty to the invention covered by the claim i.e. subject matter defined by the claim.

While some references do not show every detail of an invention claimed in an application, the differences between the two may be so slight that the invention claimed is obvious in view of the reference. Where the differences could have been made using the ordinary skill of one versed in the art, the claims are rejected for obviousness in view of the state of the prior art revealed in the reference or references.

Care must be exercised in assessing whether the differences between the claimed invention and the disclosure of the prior art, even if minor, produce unexpected results, in which event the element of unobviousness could be present.

It may be necessary to cite two or more references, or one reference and evidence of common knowledge to show all the features of an applicant's invention. Several references may be cited to show that the state of the art is such that the applicant failed to make any inventive improvement when the rejection is for obviousness rather than for anticipation. The references cannot be from such diverse arts that one skilled in the art of the invention claimed would not normally be expected to be aware of it. There may be invention in applying known principles of one art to another art if the different arts are sufficiently remote from each other, even though one skilled in the art would be expected to look beyond the immediate environment of the invention

It has been held by the courts to be obvious to do any of the following:

(a) To merely substitute superior for inferior materials, in the manufacture of one or more or all of the parts of a machine or manufacture.

(b) To merely change the size or dimensions of an object.

(c) To omit one or more of the parts of a machine or manufacture with a corresponding omission of function, unless that omission causes a new mode of operation of the parts retained.

(d) To change a process, machine, manufacture or composition of matter, by substituting an equivalent for any of its parts, unless the new part not only performs the function of the part for which it was substituted, but also performs another function, by another mode of operation, or develops new uses and properties of the article formed.

(e) To merely use an old process, machine or manufacture for a new but analogous purpose.

(f) To change the form or proportions of a machine or manufacture, unless a new mode of operation or function results.

(g) To produce an article which differs from an older article only in excellence of workmanship.

(h) To duplicate one or more of the parts of a machine or manufacture unless the duplication causes a new mode of operation, or produces a new unitary result.

(i) To combine old devices into a new machine or manufacture, without producing any new mode of operation.

15.02 Internal priority

A Canadian application may be used as a basis for priority for claims in subsequently filed applications within Canada (subparagraph 28.1(1)(a)(i) and subsection 28.1(2) of the *Patent Act*). In order to establish a priority claim, the filing date of the subject application must be within twelve months of the filing date of the preceding Canadian application (subsection 28.1(1)(b) of the *Patent Act*), and the request for priority must be made within a four month period after the filing of the subject application (paragraph 88(1)(b) of the *Patent Rules*). Where the subject matter of a claim is disclosed in more than one preceding Canadian or foreign application a priority claim may only be made if the subject application is filed within 12 months of the earliest filed application (paragraph 28.4(4)(a) of the *Patent Act*).

15.03 Claim Date

The claim date of a claim in an application or patent is the filing date of the application in Canada, unless there is a priority claimed. In the latter case the claim date is the filing date of the earliest priority application which supports the subject matter of the claim.

In order to have a valid priority claim date the following conditions must be satisfied:

a) the previously filed Canadian or foreign application must disclose the subject matter defined in the claim of the subject application (subparagraph 28.1(1)(a)(i) and (ii) of the *Patent Act* and chapter 7 of this Manual);

b) the subject matter of the claim must be reasonably inferred from supported by the specification or drawings as they were originally filed in the preceding Canadian or foreign application (section 38.2(2) and (3) of the *Patent Act*);

c) the filing date of the subject application must be within twelve months of the filing date of the preceding Canadian or foreign application (section 28.1(b) of the *Patent Act*);

d) a request for priority must be made within a four month period after filing the subject application (section 28.4 of the *Patent Act*, paragraph 88(1)(b) of the *Patent Rules*), the applicant must provide the Commissioner with the date and country of filing of each previously regularly filed application on which the request for priority is based before the expiry the four-month period after the filing date of the subject application. The applicant must also provide the Commissioner with the application number of any such application before the expiry of the later of the four-month period after the filing date of the subject application and the twelve-month period after the filing date of the previously filed application; and

e) upon requisition by the examiner, the applicant must provide a certified copy of any foreign application that forms a basis for the priority request (section 89 of the *Patent Rules*).

A situation may arise where an application may contain claims having different claim dates. This may occur when an applicant requests priority from two or more preceding applications, or when only part of the application has priority from a preceding application (section 28.4(4) of the *Patent Act*). A claim that defines subject matter in the alternative may be derived from several priority documents. In such a circumstance each alternative in the claim will be considered as a separate claim and will possess its own claim date (section 27(5) of the *Patent Act*).

15.04 Grace period

The public disclosure of claimed subject matter by the applicant, or by a person who obtained knowledge of this subject matter directly or indirectly from the applicant, will not be used to object to claims for lack of novelty or obviousness unless such disclosure was made more than one year (grace period) before the Canadian filing date (section 28.2(1)(a) of the *Patent Act*). For applications filed on or after October 1, 1996, any publication arising from an applicant's corresponding application in a foreign jurisdiction will not constitute a bar if the Canadian application is filed within 12 months of the publication (subsection 28.2(1)(a) of the *Patent Act*). For applications filed prior to October 1, 1996, any patent arising from an applicant's corresponding application in a foreign jurisdiction constitutes a bar unless (1) the Canadian application was filed before the foreign patent issued or (2) the foreign patent issued within 12 months after the filing of the first corresponding application by that inventor (subsection 27(2) of the *Patent Act* as it read prior to October 1, 1996).

15.05 Citation of art

Art cited in examiners' reports falls into two categories, that applied against the application as a basis for objection or amendment, and that cited as of interest only. Art that is applied is usually placed near the start of the examiner's report under the heading "References Applied". An examiner may also place on record related art of interest that shows the state of the art.

15.05.01 References applied

References may be applied because they disclose the invention claimed in the application (section 28.2 of the *Patent Act*), or because they show that the claims define something that is obvious and therefore unpatentable (section 28.3 of the *Patent Act*).

15.05.02 References of interest

All references placed on record that are not relied upon as grounds for objection, or to requisition amendments, are cited to show the state of the art. They may be useful in identifying subject matter disclosed but not claimed by an applicant and which cannot be claimed through subsequent amendment of the application. On some occasions, the abstract of a document which appears pertinent will be cited as a reference of interest when the full document is not available to the examiner.

15.05.03 Identification of art cited

When a reference is first cited against an application, it is identified sufficiently so that the applicant will be able to locate it. For a publication, the author, title, publisher, date of publication and page number are normally given. In the case of a patent, the number, country, date on which it became available to the public and name of inventor or patentee (if known) are given. Sometimes, as in the case of United States patents, the patent classification at the time of issue is also listed. If specific pages of the disclosure or certain views in the drawings are relied upon, they are identified.

15.05.04 Incorrect citation of references

When the Patent Office discovers that a reference has been incorrectly cited in an examiner's action which has already been sent to the applicant, a letter of correction is sent to him. Such a letter does not extend the time set for replying to an outstanding action, but if the applicant finds that as a result of the original error he is left with insufficient time to deal with the citation properly he may so indicate in his response. Under these circumstances, the objection made in view of the citation will be repeated in a subsequent action, thus giving the applicant a further opportunity to consider it.

15.06 Manner of citing references

Any patent, opened patent application, printed publication or public knowledge anywhere, disclosing the subject matter of the claim, and which disclosure was available to the public prior to the claim date of the subject application filed in Canada, constitutes a bar to the grant of a patent on that application, unless such disclosures originate from the applicant and comes within the grace period (section 28.2(1)(a) of the *Patent Act*). Therefore, public disclosures of the invention by the applicant or by a person who obtained knowledge of the invention, directly or indirectly from the applicant and which disclosures occurred more than one year before the Canadian filing date (grace period) of the application are also a bar. These disclosures are considered eligible citations both for lack of novelty and obviousness. The applicant is given the opportunity to overcome the citation by amendment to clear the reference or by presenting convincing arguments showing that the invention claimed differs patentably from that described in the cited reference.

For example, under section 28.2 of the *Patent Act* claims are objected to if the subject matter was:

(i) disclosed by the applicant, or by a person who gained knowledge of the invention from the applicant, so as to be available to the public more than one year prior to the Canadian filing date (section 28.2(1)(a) of the *Patent Act*), or

(ii) disclosed by another person so as to be available to the public before the claim date.

However, a foreign application of the same inventor disclosing the same invention as the corresponding Canadian application, and which was published, laid open, or granted prior to the Canadian filing date, is a bar to the grant of the Canadian Patent, unless the Canadian application was filed within twelve months of such foreign publication or granting (grace period).

15.06.01 Citations of copending Canadian applications

A laid open copending application by a different applicant describing the same invention and having at least one claim with an earlier claim date then a subject application will be cited as a document that negates the novelty of the claims of the subject application (paragraph 28.2(1)(d)). However, a copending application cannot be cited against a subject application on the grounds of obviousness, unless the subject matter of the copending application was made available to the public prior to the claim date of the subject application. In this section, the subject application is the application under examination.

In the event that two or more copending applications describe the same invention the following situations may arise:

(A) No examination request on any application:

No consideration will be given to the copending applications until examination has been requested for at least one of the applications.

(B) Subject application is the earlier filed application:

(i) where the subject application has a Canadian filing date that predates the claim date of any other copending applications, no consideration will be given to the other copending applications and examination of the subject application will proceed as though they did not exist;

(ii) where any copending application has at least one claim date earlier than the Canadian filing date of the subject application then the relevant claim dates of the subject application and copending application need to be verified (section 89 of the *Patent Rules*);

(C) Subject application is the later filed application:

where the subject application has a Canadian filing date that is preceded by the claim date of any other copending application describing the same invention, then;

(i) where the copending application having the earlier claim date has been laid open to the public in Canada or in any other country before the claim date of the subject application, then the copending application or its foreign counterpart having the earlier claim date is cited against the subject application as a publication;

(ii) where the copending application having the earlier claim date was not available to the public in Canada or in any other country before the filing date of the subject application, the copending application is cited under paragraph 28.2(1)(c) or (d) of the *Patent Act* after the copending application is laid open. Verification of the claim dates of the copending and the subject application is necessary. The copending application cannot be cited against the subject application as a reference for obviousness since the disclosure of the subject matter was not available to the public at the claim date of subject application (subsection 28.3(b) of the *Patent Act*).

(D) Overlap between copending applications of the same applicant:

Where an examination request is received for an application and there is an application by the same applicant describing and claiming the same invention having an earlier claim date then:

(i) Where the application having the earlier claim date has been made available to the public in Canada or in any other country more than one year (grace period) before the application under examination was filed in Canada, then the application having the earlier claim date would be applied against the subject application in the same manner as any other citable published material;

(ii) Where the application having the earlier claim date has not been made available to the public for more than one year before the application under

Examination was filed in Canada, the application having the earlier claim date would be cited requisitioning the applicant to remove the overlapping claimed subject matter. The citation for overlapping subject matter is applied irrespective of whether or not internal priority has been established on the previously filed application. Since the term of protection initiates from the filing date and not the claim date, the applicant must choose in which application to prosecute the overlapping subject matter in order to prevent extension of the exclusive right (sections 44 and 45 of the *Patent Act*). This precludes using the applicants' earlier filed application against his/her own later filed application(s) ("self collision").

15.06.02 Copending PCT applications

Applications filed under the provisions of the Patent Cooperation Treaty are a special case in regard to their copendency with other Canadian applications. Section 63 of the *Patent Rules* particularly indicates that such applications will be deemed to be applications filed in Canada at the time they become national phase applications.

For the purpose of a citation under section 28.2(1)(c) and (d) of the *Patent Act* in the prosecution of another application, a PCT application will benefit from its filing date or priority date only after it has entered the national phase. This could be 20 months after the filing date of the international application but may be delayed up to 42 months in certain circumstances. Should an examiner wish to cite a PCT application the status with respect to national entry in Canada must first be verified. If such application has not entered the national phase, it may be cited only as a publication using the international publication date.

15.07 Jurisprudence

The following decisions of the courts are of importance in considering the subject matter of this chapter:

Obviousness/Anticipation

Fada Radio v CGE	SCR	520	1927
Christiani v Rice	Ex CR	111	1929
	SCR	443	1930
	RPC	511	1931
Mico Products v Acetol	Ex CR	64	1930
Crosley Radio v CGE	SCR	551	1936
K v Uhleman Optical	Ex CR	142	1950
	1 SCR	143	1952
Comm of Pat v Ciba	SCR	378	1959
Lovell v Beatty	41 CPR	18	1962
Defrees v Dominion Auto	Ex CR	331	1963
Lamb Sets v Carlton	Ex CR	377	1964
Comm of Pat v Farbweke	SCR	49	1964
Gibney v Ford	2 Ex CR	279	1972
Xerox v IBM	33 CPR (2d)	24	1977
Marzon v Eli Lilly	37 CPR (2d)	37	1978
Globe Union v Varta	57 CPR (2d)	132	1978
Reeves Bros v Toronto	43 CPR (2d)	145	1978
Farbwerke v Halocarbon	2 SCR	929	1979
	74 CPR (2d)	95	1983
Beecham v Procter & Gamble	61 CPR (2d)	1	1982
Cutter v Baxter Travenol	68 CPR (3d)	179	1983
	74 CPR (2d)	95	1983
Johnston Controls v Varta	80 CPR (2d)	1	1984
Windsurfing v Bic Sports	8 CPR (3d)	241	1985
Beloit v Valmet	8 CPR (3d)	289	1986
Sandvick v Windsor	8 CPR (3d)	433	1986
Tye-Sil v Diversified	16 CPR (3d)	207	1987
	35 CPR (3d)	350	1991

Reading & Bates v Baker	18 CPR (3d)	181	1987
	35 CPR (3d)	350	1991
Apotex v Hoffman-La Roche	15 CPR (3d)	217	1987
	24 CPR (3d)	289	1989
Brushtech v Liberty	23 CPR (3d)	370	1988
Gorse v Upwardor	25 CPR (3d)	166	1989
	40 CPR (3d)	479	1992
AT&T Tech v Mitel	26 CPR (3d)	238	1989
Control Data v Senstar	23 CPR (3d)	449	1989
Lubrizol v Imperial Oil	33 CPR (3d)	1	1990
	45 CPR (3d)	449	1992
Procter & Gamble v Kimberly	40 CPR (3d)	1	1991
Martinray v Fabricants	14 CPR (3d)	1	1991
Rothmans, Benson & Hedges	35 CPR (3d)	417	1991
Procter Gamble v Kimberly	40 CPR (3d)	1	1991
Re: Hering's Application	53 CPR (3d)	390	1992
	47 CPR (3d)	188	1993
Atlas v CIL	41 CPR (3d)	348	1992
Allied v Du Pont	52 CPR (3d)	351	1993
	50 CPR (3d)	1	1993
CFM v Wolf Steel	50 CPR (3d)	215	1993
	64 CPR (3d)	75	1995
Hi-Quail v Rea's Welding	55 CPR (3d)	224	1994
Anderson v Machineries	58 CPR (3d)	449	1994
Almecon v Nutron	65 CPR (3d)	417	1996

"What would infringe later, anticipates earlier"

Lightning Fastener v Colonial	Ex CR	89	1932
	SCR	363	1933
	51 RPC	349	1934
EMI v Lisen	56 RPC	23	1939
Atlas Copco v CIL	41 CPR (3d)	348	1992
CFM v Wolf Steel	50 CPR (3d)	215	1993
	64 CPR (3d)	75	1995

subject matter reasonable inferred

Re Application No. 139,256	51 CPR (2d)	95	1977

overlapping subject matter/double patenting

Short Milling v George Weston	Ex CR	69	1941
Rohm & Haas v Comm of Patents	30 CPR	113	1959
Lovell v Beatty	41 CPR	18	1962
Boehringer v Bell-Craig	39 CPR	201	1962
Comm of Pat v Farbweke	41 CPR	9	1963
	SCR	49	1964
Xerox v IBM	33 CPR (2d)	24	1977
Consolboard v MacMillan	56 CPR (2d)	145	1981
	1 SCR	504	1981
Beecham v Procter & Gamble	61 CPR (2d)	1	1982
Re: Hedstrom	31 CPR (3d)	324	1989

types of prior art (printed documents, experimental use etc.)

Gibney v Ford	2 Ex CR	279	1972
Leithiser v Pengo Hydra-Pull	12 CPR (2d)	117	1973
	2 FC	954	1974
Xerox v IBM	33 CPR (2d)	24	1977
Koehering v Owens-Illinois	40 CPR (2d)	72	1978
	52 CPR (2d)	1	1980
Beecham v Procter & Gamble	61 CPR (2d)	1	1982
Johnston Controls v Varta	80 CPR (2d)	1	1984
J M Voith v Beloit	27 CPR (3d)	289	1989
Beloit v Valmet	36 CPR (3d)	322	1991
Hi-Quail v Rea's Welding	55 CPR (3d)	224	1994

Chapter 16
Computer-Implemented Inventions

16.01 Scope of this chapter

The purpose of this chapter is to highlight Office practice as it pertains in particular to computer-implemented inventions.

The term "computer" is used in this chapter to refer to an electronic device comprising a processor, such as a general-purpose central processing unit (CPU), a specific purpose processor or a microcontroller. A computer is capable of receiving data (an input), of performing a sequence of predetermined operations thereupon, and of producing thereby a result in the form of information or signals (an output).

Depending on context, the term "computer" will mean either a processor in particular or can refer more generally to a processor in association with an assemblage of interrelated elements contained within a single case or housing.

Guidance provided herein in respect of "computers" may apply, where the term has been used to refer to a device comprising a processor, to devices such as network servers, personal digital assistants (PDA), multi-function cell phones, and the like, or even to processor-containing televisions, music or video playback devices and appliances such as bread makers or coffee machines.

In certain contexts, the term "computer" may be used to encompass a device interacting with certain ubiquitous peripherals, such as a keyboard, mouse or display, necessary for interacting with the computer itself. In this sense, the term "computer" may refer to a "general purpose computer" such as a desktop or laptop computer capable of receiving input, such as via a keyboard, and providing output, such as to a display means.

Where references are made to software "stored on" a physical memory, these are intended to simply refer to the fact that the physical memory is storing the software. No distinction is made herein between memory types which are best described as having software "stored in" the memory and those that are best described as having the software "stored on" the memory.

In reading this chapter, it should be borne in mind that its purpose is to clarify, through elaboration, the application of the more generic teachings of other chapters to the particular issues encountered with computer-implemented inventions.

Nothing in this chapter should be interpreted as providing exceptions to any practice of general applicability set out in any other chapter. Throughout this chapter, reference is made to the nature of the contribution in a claimed invention. Additional guidance on the contribution approach used to assess whether a patentable contribution has been made can be found in Chapter 13 of this manual.

16.02 Subject-matter

As with any invention, in order to be patentable under the *Patent Act* the claimed subject-matter of a computer-implemented invention must fall within one of the five categories found within the section 2 definition of "invention", namely art, process, machine, manufacture or composition of matter.

The following sections set out how the five categories of invention apply to computer-implemented inventions in particular, and consequently refine the more general guidance provided in Chapter 12 of this manual.

A computer-implemented invention may be claimed as a method (art, process or method of manufacture), machine (generally, a device that relies on a computer for its operation), or product (an article of manufacture). Certain subject-matter relevant in the computer arts may not be claimed as such, including computer programs [16.08.04], data structures [16.09.02], and computer-generated signals [16.09.05].[1]

A guiding principle in respect of computer-related inventions was provided by the Federal Court of Appeal in *Schlumberger*, which noted that "the fact that a computer is or should be used to implement a discovery does not change the nature of that discovery", and also that the presence of a computer cannot effect the "transforming into patentable subject-matter [of] what would, otherwise, be clearly not patentable".[2]

16.02.01 Art

Computer-implemented inventions falling within the category *art* are typically claimed as methods.

Many methods involve the use of a computer or an apparatus or device including a computer. A method that, on its own merits, would be considered non-statutory does not become statutory simply by virtue of some part of the method being carried out on or by a computer. The method itself, as a whole, must be a solution to a practical problem and must lie within a field of technology.

Claims to computer-implemented methods for playing games or creating works of art do not define inventions that belong to a field of technology and do not come within the definition of invention in section 2 of the *Patent Act* [see sections 12.06.05 (Games) and 12.06.03 (Fine arts) of this manual].

A method of controlling a computer's operations so as to achieve a technological result,[3] in contrast, would come within the definition of invention in section 2 of the *Patent Act*. In such a method, the electronic processes within the computer are considered to satisfy the requirement that the method include (either explicitly or implicitly) at least one act performed by a physical agent upon a physical object, producing in that object some change of condition.

16.02.02 Process

As noted in section 12.02.02 of this manual, a *process* implies the application of a method to a material or materials. To be statutory, a process must apply a statutory method.

When assessing the contribution of a computer-implemented process, it must be borne in mind that the necessary ingenuity can arise from the method, from the material or materials, or from the recognition that applying the method to the material or materials leads to an unexpected useful result.

16.02.03 Machine

A device such as a computer, or an apparatus or system including a computer associated with other devices, is generally viewed as falling within the category *machine*.

Whether or not a claim to a device defines a patentable invention depends on the presence of a contribution in the claimed matter and the nature of this contribution [see section 13.05.03 of this manual]. As noted in section 13.05.03*b*, for a claim to be patentable it must define at least one statutory element that forms part of the contribution. For a claim to a device to be patentable, the device itself must therefore be a contributed practical form. That is, the device must provide a novel and unobvious technological solution to a technological problem.

Determining whether or not this is the case can be performed by assessing the device itself, but in many cases can also be performed indirectly by reference to the method implemented by the device. Where a statutory method is implemented by a computer, apparatus or system, a device capable of implementing the entire method is necessarily a solution to a practical problem. Presuming the device has been specifically modified to implement the method, such that it is novel and unobvious, it will be a statutory contribution. The patentability of a device is not negated, however, from the mere fact that the device is intended to implement or to be used in a non-statutory method. The question to be addressed in such cases remains whether the device provides a novel and inventive technological solution to a technological problem.

Where a device does provide such a solution, its patentability does not depend on whether it was adapted by providing new hardware or by controlling existing hardware in a particular manner by the addition of software or firmware (software programmed into a read-only memory).

Note that the "technological solution to a technological problem" does not have to be in relation to the operation of the computer as a general purpose device (e.g. it is not necessary that a computer be made more efficient or reliable), but could be simply that the general purpose device has been technologically adapted to act as a special purpose device. Thus, presuming novelty and ingenuity, any of the following provide technological solutions to technological problems and would be viewed as contributed devices: a computer programmed to allow its speakers to simulate "surround sound" (known hardware controlled by new software), a computer adapted to operate using two central processing units (new arrangement of known hardware, controlled by new software), a computer programmed to allocate memory to video processing in a manner that increases the efficiency of the device when running several applications (known hardware controlled by new software), and a computer whose motherboard has an inventive new video card slot with a faster data transfer rate (new hardware).

Where a computer or other device does not provide a solution to a technological problem, the computer or device as a whole is not a contributed practical form of an invention. Where such a device is further defined in terms of discrete non-statutory features, the claim would be objected to on the ground that it does not define a statutory "invention" within the meaning of section 2 of the *Patent Act* [see section 13.05.03*b* of this manual]. For example, a computer or other programmable device cannot be patentably distinguished from other computers simply on the basis of stored information; the stored information does not cause the computer to become a new and unobvious solution to a practical problem [see section 12.06.07 of this manual].

16.02.04 Manufacture

The category *manufacture* encompasses both processes for manufacturing and the products made by such processes [see section 12.02.04 of this manual]. As noted in 16.02.03, a device including a CPU is generally viewed as falling within the category *machine*. The category *manufacture* is therefore considered to apply to computer-implemented inventions either where a computer is used to control a manufacturing process, or where a non-*machine* computer product is claimed. The principles discussed in 16.02.02 apply equally to computer-controlled manufacturing *processes*.

The concept of a non-*machine* computer product applies to a physical memory storing computer-executable instructions. A computer program *per se* is not statutory because it is disembodied. A physical medium storing the program, however, may be considered a *manufacture*. The patentability of such products depends on the nature of the contribution, and is discussed in 16.08.04.

16.02.05 Composition of matter

The category of invention *composition of matter* relates to chemical compounds, compositions and substances and is not of great significance to computer-implemented inventions. A computer-controlled method or process for manufacturing compositions of matter could be evaluated under the category *art* or *process* as the case may be.

16.03 Examining computer claims

A patentable claim must include a statutory contribution. Where a claim is directed to a computer, it must be determined whether the device itself is part of the contribution - that is, whether the computer itself may be considered novel and inventive.

In evaluating whether the computer has been contributed, it is first necessary to identify the essential elements of the device; *i.e.*, those that, as a set, provide a technological solution to a technological problem [see section 13.05.03 of this manual]. For the computer to be patentable, this set of elements must be novel and inventive.

As noted in 16.02.03, where the machine has been specially adapted to implement the entirety of a patentable (statutory, useful, novel and inventive) method, the machine is considered to be a technological solution and is patentable.

Where a machine implements a non-statutory method, in contrast, inventive ingenuity associated with the method *per se* does not provide the inventive step necessary to support the patentability of a machine implementing that method. The inventive ingenuity necessary to make the machine patentable must arise in relation to adapting the machine to implement the method.

16.03.01 Adapting a computer to solve a problem

A computer can be adapted to solve a problem either by its hardware, software or a combination thereof. Where the adaptation is performed via hardware, this will typically permit a structural comparison of the computer to other computers and will facilitate the assessment of novelty and ingenuity.

More often, however, a computer will be adapted via software. In evaluating whether a computer adapted by software is the result of ingenuity, it is useful to draw a distinction between the design of a computer program and the expression of that program in a specific programming language.

Designing a computer program comprises steps such as developing a method to be implemented by the computer and creating flow charts, design diagrams or pseudocode to describe the method steps to be performed by the computer in order to solve a problem. Furthermore, specific operations and their necessary sequence to enable the computer to implement the method are determined.

Once the design is completed, the computer program is expressed as lines of code. Expressing a computer program in a specific programming language, however, is considered to fall within the common general knowledge of an uninventive skilled programmer and is not considered to require inventive effort. This person skilled in the art is considered to be able to express the program in any number of different programming languages without the exercise of judgement or reasoning, and therefore without the exercise of ingenuity. Consequently, the inventive ingenuity necessary to provide patentability to a computer is never found simply in writing computer code to express a developed program.

16.03.02 Patentability and programming

A computer program is not, by itself, statutory subject-matter. However, if the result of running the program on a computer is to provide a novel and inventive technological solution to a technological problem, then the program is viewed as modifying the technological nature of the computer as a whole. The program in such cases is not a discrete element of a claim to the computer.

In considering whether a program will bestow patentability on an otherwise-known computer, the goal is therefore to identify whether it provides a novel and inventive technological solution to a technological problem.

In cases where the computer program expresses a statutory method (*i.e.* a series of steps which provides a technological solution to a technological problem), the program will be considered to be technological in nature. If the method is also both novel and inventive, then the programmed computer would be patentable. Thus, as noted in 16.02.03, where a computer implements the entirety of a patentable method, the computer is patentable. If the method, while technological, is not novel and inventive then it is not sufficient to render the computer patentable. Note that where the computer only implements part of a patentable method, care must be taken to base the assessment only on those parts of the method which take place on the computer, and not on the basis of the method as a whole.

On the other hand, where the computer program expresses a non-statutory method, the non-statutory method itself is not a patentable contribution, regardless of whether it is novel and inventive. The patentability of the computer claims in such cases will depend on additional elements defining how the computer is adapted to implement the method. These additional elements may or may not be novel and inventive, depending on their nature and complexity and the state of the art in programming at the relevant date. Where inventive effort is needed to enable a computer to implement a method in a novel way, a technological solution to a technological problem has been contributed.

In determining whether the program's design is inventive or not, the examiner will be guided by the description. Paragraph 80(1)(*d*) of the *Patent Rules* states that the description shall "describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution".

Thus, it should be clear from the description what technical (technological) problem is being addressed, and what solution is being proposed by the inventors. Where the examiner is considering whether ingenuity was required in reducing an algorithm to a specific series of operations to be carried out by the computer program, the level of detail included in the description will be informative.

Where the application includes no details regarding how the computer program is to operate, this suggests the applicant considers the manner of implementing their method to be uninventive. It can be appropriately concluded by the examiner that there is no invention in the reduction to practice of the method. This conclusion is not prejudicial to the applicant, since even if the applicant were incorrect in considering the development of the program to be uninventive it would nevertheless follow that the description would not be enabling. Given the lack of disclosure, the programmer would be called upon to exercise inventive effort in determining how the program is to operate.

Where a greater level of detail is provided, the examiner must consider whether the specific implementation is an inventive solution to a technological problem in respect of the operation of the computer, and thereby determine if the computer itself has been contributed.

16.03.03 Examples

The following examples illustrate how the guidance in this chapter can be applied in practice, particularly where the subject-matter of the invention lies outside the field of computers *per se*.

Example 1:

An application discloses the atomic coordinates of protein X and a crystal structure of said protein. A three-dimensional molecular modelling algorithm is applied to the atomic coordinates to determine the spatial coordinates of the binding pocket of protein X and subsequently, *in silico* screening is performed to search for compounds that interact with protein X.

Prior art document D1 discloses:

- molecular modelling software capable of generating a 3D representation of a binding pocket from the atomic coordinates of a protein,
- that the software is capable of performing *in silico* screening to predict whether known molecules will bind with the binding pocket, and
- databases storing the atomic coordinates of various molecules.

Claims:

1. Atomic coordinates of protein X.

2. A computer readable medium comprising the atomic coordinates of claim 1.

3. A computer-implemented method for identifying compounds that interact with protein X, comprising the steps of:
    a. generating on a computer a three-dimensional model of protein X from the atomic coordinates of claim 1;
    b. identifying a binding pocket in the model of protein X;
    c. searching within a database of structurally defined compounds to identify compounds that are structurally complementary to the binding pocket of protein X;
    d. calculating the binding energy for each structurally complementary compound identified in step (c) to the binding pocket of protein X; and
    e. generating an output identifying compounds with binding energies meeting preselected conditions.

Analysis: Claim 1 defines atomic coordinates, which are merely descriptive information relating to the protein. The claim is not, by its form, directed to a statutory invention under section 2 of the *Patent Act*. Claim 2 defines this information when stored on a carrier. It is statutory in its form, but does not include a statutory contribution (the storage medium itself being, self-evidently, known).

Claim 3 defines a method whereby a computer generates a 3D model of a molecule, analyses the model to identify a binding pocket, and attempts to find target molecules whose structures are complementary to the binding pocket and which will bind to the binding pocket. Several of the steps involve computer operations that could potentially be technological innovations in the operation of a computer, including generating the 3D model (step a), analysing the model to identify a binding pocket (step b), and performing the shape-matching and energy minimization calculations (steps c and d). Claim 3 is directed, by its form, to a statutory method. In view of D1, however, these operations are already known and therefore do not form part of the contribution. The specific atomic coordinates of protein X do not modify the technological manner by which the computer performs the calculations, and therefore the model of protein X is a discrete element of the claim. The model of protein X is not itself a statutory invention (could not be a statutory contribution). After having set out a contribution analysis, in view of D1, the claim can be found defective under section 2 of the *Patent Act* on the basis that no contributed statutory subject-matter has been defined and the model of protein X is not a statutory invention.

The analysis of claim 3 would be guided by the description of the application. The level of detail provided in respect of how the computer performs the various modelling, analysis, shape fitting and energy minimization steps would be indicative of whether technological obstacles were overcome by the inventors in respect of these operations. A lack of detail, or for example a reference to the known molecular modelling software of D1, would be a strong indication that there was no innovation in how the computer performed these operations. Note that if specific details were given in respect of how the computer operations were performed, these would need to be claimed in order to distinguish the method from that of D1.

Note that the conclusion with respect to claim 3 is arrived at after having performed a contribution analysis, in view of the substance of the claimed invention. This can be contrasted with the statement made with respect to the claim in example 5 in section 17.02.04 of this manual, which indicates only that, by its form, that claim is directed to a statutory method.

Example 2:

An application discloses a vehicle wheel alignment system comprising a vehicle station used for vehicle testing, a set of optical sensors for measuring vehicle wheel alignment angles, an automated tool for adjusting wheel angles, and a computer station. Aligning vehicle wheels is a process which includes measuring and adjusting a number of wheel angles, such as camber, caster and toe angles, as well as the steering axis inclination. The computer runs software which compares angles measured by the optical sensors with manufacturer-recommended specifications stored in a database and produces an output signal which instructs the automated tool to perform a synchronized adjustment of any wheel angles that are outside predetermined limits. The automated tool is a single unit comprising several modules, with each module being capable of adjusting one of the wheel angles.

The prior art search reveals that the following features are known:

- a vehicle station used for alignment of vehicle wheels,
- measuring wheel alignment angles using a set of optical sensors,
- inputting the measured values to a computer,
- searching a database to determine if the measured angles meet manufacturer recommendations,
- the use of a computer to calculate required wheel angle corrections; and
- a tool for adjusting wheel angles.

The prior art does not disclose an automated tool for the synchronized adjustment of multiple wheel angles, comprising several modules in a single unit wherein each module adjusts a specific wheel angle.

Claims:

1. A method for vehicle wheel alignment comprising the steps of:
    a. measuring vehicle wheel alignment angles using a set of optical sensors,
    b. inputting the measured alignment angle values into a computer,
    c. searching for corresponding manufacturer recommended wheel angles stored in an electronic database,
    d. calculating differences between the measured values and the corresponding manufacturer recommended angles,
    e. producing a signal to actuate an automated tool for angle alignment, said signal being based on the calculated differences, and
    f. synchronously aligning wheel angles on the vehicle using the actuated tool.

2. A system for vehicle wheel alignment comprising:
    a. a set of optical sensors for measuring vehicle wheel alignment angles;
    b. an automated tool for the synchronous adjustment of vehicle wheel angles, the automated tool being a single unit comprising several modules, with each module being capable of adjusting a specific wheel angle; and
    c. a general purpose computer in electronic communication with the optical sensors and the automated tool, wherein the computer comprises:
        i) means for receiving inputted data,
        ii) means for retrieving manufacturer recommended wheel angle values from an electronic database,
        iii) means to calculate differences between the measured values of the vehicle wheel alignment angles and the manufacturer recommended angles, and
        iv) means to output a signal based on the calculated values to actuate the automated tool in order to synchronously align the vehicle wheel angles.

3. A method for calculating a vehicle wheel angle condition comprising the steps of:
    a. inputting measured values of vehicle wheel angles into a computer,
    b. searching for corresponding manufacturer recommended wheel angles stored in an electronic database,
    c. calculating differences between the measured values and the recommended values, and

d. displaying the calculated angle differences on a computer display.

4. A system for calculating a vehicle wheel angle condition comprising:
   i) an input means for inputting measured values of vehicle wheel angles,
   ii) a processor means for searching for corresponding manufacturer recommended angles stored in an electronic database and for calculating differences between the measured values and the manufacturer recommended angles, and
   iii) an output means for displaying the calculated angle differences on a computer display.

Analysis: Claim 1 defines a method involving the application of physical steps to solve a technological problem - how to align the various wheel angles synchronously rather than sequentially. The method, when considered as a whole, is statutory in form. The prior art discloses measuring wheel alignment angles, comparing the measured values to a database and performing the alignment sequentially in respect of each angle. There is no prior disclosure of performing the alignment synchronously. The patentability of the method depends on whether the examiner considers step f, which is novel, to also be inventive. Since the patentability of this claim depends on whether a statutory step is considered to be inventive, the critical assessment can be made under section 28.3 of the *Patent Act*.

Claim 2 defines a system to perform the method of claim 1. If the system has been specifically adapted in order to perform the method (in this case, the use of multiple modules in a single unit suggests that this is the case), then its patentability depends on the same factor of inventiveness as claim 1. As noted in 16.02.03, a machine specifically adapted to perform the entirety of a patentable method is patentable.

Claim 3 defines a method for performing calculations in order to obtain information. By its form, the claim includes physical steps that could, in theory, be patentable. It is clear, however, that the technological aspects of each step (how to input data on a computer, how to search databases, how to solve a simple algebraic equation on a computer, how to display a result) are known and form part of the common general knowledge in the art. In view of the common general knowledge in the art, it can be readily concluded that, in substance, the invention in claim 3 amounts to a mental method performed by a computer. Following 16.02.01, the addition of a computer does not make a non-statutory method statutory. Having determined that no statutory subject-matter has been contributed, the defect associated with claiming a mental method is identified under section 2 of the *Patent Act*.

Claim 4 defines a computer capable of performing the method of claim 3. For it to be patentable, some technological advance would have to have been made in the operation of the computer itself. The claim defines “an input means for inputting”, “a processor means for searching ... and calculating" and "an output means for displaying". These are the discrete statutory elements of the system and represent hardware and software components capable of performing the stated functions. The remaining features of the claim pertain to what values are to be inputted, looked up, used in the calculations and displayed. These features have purely intellectual significance and do not define how the system is operated as a technological entity. As drafted, it is self-evident that the technological functionality required of the defined statutory means is present in a general purpose computer. The claimed matter lacks novelty in view of the common general knowledge in the field of computers and does not comply with section 28.2 of the *Patent Act*. The claim can also be considered defective under section 2 of the *Patent Act* for attempting to distinguish over known subject-matter by features having a solely intellectual significance.

16.04 Utility

An invention must be useful, in the sense of doing whatever was promised by the inventors. The utility of the claimed subject-matter must be established by demonstration or sound prediction, and this subject-matter must be operable to produce the promised result in a manner that is controllable and reproducible.

A computer is generally considered to be capable of reproducibly performing whatever operations its hardware and programming enable. The utility of a computer-implemented invention is not guaranteed by this fact, however. Even where the components of the computer are working as intended, the invention as a whole may require other elements for its proper operation.

Where the judgement or interpretative reasoning of an operator is implicated in the proper operation of the claimed invention, such as deciding on suitable computer-managed operations through the exercise of judgement and reasoning, the criterion of reproducibility will not be satisfied. Where an operator's input is required, but there is no judgement associated with the input, the need to rely on the input does not cause a lack of reproducibility [see section 12.08.02 of this manual].[4]

Where a computer-implemented method is being claimed, it must be unambiguously clear which steps of the method are being carried out on or by a computer [see 16.08.01].

16.05 Sufficiency

The general requirements for a sufficient disclosure of an invention are detailed in Chapter 9 of this manual, and apply equally to computer-implemented inventions as to any other.

Certain aspects of a correct and full description of a computer-implemented invention warrant particular attention, and are discussed in the following sections.

16.05.01 Written description and enablement

In accordance with subsection 27(3) of the *Patent Act*, the specification must correctly and fully describe the invention. In practice, this requirement relates to the description, which must support the claims in accordance with section 84 of the *Patent Rules.*

The two requirements of a description are i) that it disclose in clear and unambiguous terms the nature of the claimed invention (written description requirement) and ii) that it provide any teachings necessary to allow a person skilled in the art to operate the claimed invention (enablement requirement). A person skilled in the art must be able to understand, in view of the specification alone when read in light of their common general knowledge, what the invention is, what it does, and how to make it work.

The level of description necessary will depend on the facts of each case. In general, where aspects of common general knowledge are referred to, it may not be necessary to do more than identify a well-known element or technique forming part of this common stock of information. Where specific information is required that does not form part of the common general knowledge, this must be explicitly provided. For example, if certain hardware and software are known in the art at the date of invention, it will be obvious that they can be used to achieve known or predictable results or perform known or predictable operations. It may be possible to describe and enable those aspects of the invention that relate to this known hardware or software simply by identifying the particular hardware or software element to be used and the known or predictable result to be achieved. In contrast, if the desired result requires a novel and unobvious application of hardware or software, a greater level of detail regarding how this result is to be achieved would be necessary.

Where a claim defines the invention in terms of means-plus-function statements, the nature of the means, and where applicable how they are arranged to provide the stated functionality, must be clear to the person skilled in the art. The level of description necessary to correctly and fully describe the means, and their arrangement where applicable, will depend on the state of the common general knowledge in the art. Where limited description is provided, this is taken as an indication that the applicant (rightly or wrongly) considers that the selection of suitable means to perform the stated function would be readily apparent to a person skilled in the art.

Computer-implemented inventions are often described in terms of a flow chart that illustrates the algorithm or logic tree on which the operation of the invention is based. Typically, the flow chart will set out the operations performed by a computer. Flow charts are diagrams having a series of boxes, each representing a state or a step in an algorithm, and arrows that interconnect these boxes to describe the order or relationship of the various steps.

It will often be the case that the algorithm or logic performed by the computer lie at the heart of the invention. In such circumstances, a full description of the algorithm or logic tree should be provided. Where the algorithm or logic is described by reference to a flow chart, presented as a drawing, a written explanation of the flow chart is necessary to provide support for any claims that refer to the algorithm or logic.

In order to successfully practice the invention, it is necessary for the person skilled in the art to be able to put each step in the flow chart into operation. For the description to be enabling, the person skilled in the art must be able to do this without recourse to inventive ingenuity or undue experimentation. The flow chart, and any accompanying description, must therefore provide any information necessary to enable the algorithm to be so practised.

The amount of written description necessary to properly describe and enable an algorithm depends on the relationship of each step to the common general knowledge. Where the algorithm invokes well-known operations, it may be that very little or no specific description is necessary for the purposes of proper description or enablement. If, in contrast, the specific operations necessary to enable a step in the algorithm would not be obvious to the person skilled in the art, these operations would need to be fully described.

Furthermore, if the common general knowledge of the person skilled in the art would lead them to attempt to enable the algorithm in ways that would not in fact work, the description should provide sufficient instructions to allow the person skilled in the art to arrive at operable embodiments and avoid inoperative ones.

Where very little explanation is given regarding how a step in a method is to be implemented by a computer, this will generally be understood as an indication that the applicant, rightly or wrongly, does not consider the implementation of that step to require inventive effort on the part of the person skilled in the art.

16.05.02 Source code or pseudocode

Source code or pseudocode may be provided as part of the description of a computer-implemented invention, but will generally not be considered, by themselves, to provide a full and enabling description of an invention.

Where source code is provided, it must be remembered that the significance of the commands used in specific code may depend on the intended platform, and the code itself will generally not be a clear and unambiguous description of the invention.

Pseudocode refers to a semi-structured, natural language explanation of the functioning of an intended program, and may be used as an alternative to a flowchart to provide a set of instructions with a logical sequence but which do not follow the syntax of any particular programming language. Pseudocode will therefore usually have a greater value in describing an invention than source code in a specific programming language. However, in the same way that a flowchart will usually require an accompanying description in order to fully describe an invention, pseudocode alone will typically not be sufficient to provide a full and unambiguous description of an invention.

16.05.03 Common general knowledge and programming

The activities required to reduce a specific series of logic instructions to a computer code are considered to form part of the common general knowledge of a skilled programmer. It is, therefore, typically not necessary for an inventor to describe how to write computer code, either in general or in respect of a specific computer language.

Where the algorithm to be written out as lines of code only invokes well-known operations, or if specific and unobvious logic operations are required, where these have been clearly described, the act of expressing the specific commands as lines of code is considered not to require inventive ingenuity or undue effort.

Where the description only discloses in broad terms what the program is intended to do, and it would not be clear to the person skilled in the art in view of their common general knowledge what the required operations are or the logic necessary to enable specific required operations, then the skilled programmer has not been given sufficient instructions to create the necessary code. To create a working program, the programmer would first have to exercise ingenuity in order to solve the problem of reducing the concepts disclosed to a series of practical instructions (i.e. would need to design the program; see 16.03.01).

16.06 Novelty

As with every invention, in order to be patentable a computer-implemented invention must not be anticipated by prior art that is relevant under section 28.2 of the *Patent Act*.

To be anticipatory, a single prior written disclosure, when understood in light of the common general knowledge, must both provide a written description of the claimed invention and sufficient instructions to enable the invention to be practised by the person skilled in the art without recourse to inventive effort or undue burden.

In considering whether a claimed invention is anticipated, its essential elements must be compared to those taught in a single prior disclosure. If all its essential elements were previously disclosed, the invention is anticipated. The essential elements of an invention are those that have a bearing on what the invention will do and how it does it (i.e. on its practical and promised utility) [see section 13.05.03 of this manual].

When considering a computer device (*machine*) claim, the effect of any commands being implemented by software must be carefully considered in order to determine if they lead to a technological effect relevant to the promised utility of the device. If so, those commands are essential elements of the device, and must be considered during the novelty analysis. If the commands are simply an application of functionality the machine was already known to possess, they are not considered to be essential elements of the machine itself.

16.06.01 Anticipation by prior use

Although the majority of prior art consists of prior written disclosures, a prior sale or use of an invention can also amount to an anticipation, provided it makes available information which describes the claimed invention and amounts to an enabling disclosure.[5]

With regard to computer-implemented inventions, software that was available to the public prior to the claim date can be considered as prior art. To be considered to have disclosed the claimed invention, the software must provide to the person skilled in the art information sufficient to comprehend the invention.[6] The use of a product makes the invention part of the state of the art only so far as that use makes available the necessary information.[7] The information made available must be such that if the person skilled in the art were to write down that information, they would have drafted a clear and unambiguous description of the claimed invention.[8]

Thus, if the claimed invention is defined broadly using functional language, any prior art software that achieves the same function could be anticipatory. In contrast, if the claimed invention defines a particular method for arriving at a specific result, prior art software would only be anticipatory if it could be established, on the balance of probabilities, that it was using the same method for arriving at the result.

As was noted in *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.*, in determining whether a publicly available product anticipates a claimed invention, the ability of the person skilled in the art to reverse engineer the product "in accordance with known analytical techniques" may be relevant.[9] Therefore, where relevant, the ability of the person skilled in the art to reverse engineer software, without inventive effort, in order to ascertain what method it implements must be considered. Note that what is considered is the ability to reverse engineer, such as by decompiling; it is not necessary to establish that the product was actually reverse engineered.[10]

In considering whether anticipation by prior sale or use of an invention has occurred, the grace period provided for in paragraph 28.2(1)(*a*) of the *Patent Act* applies in respect of any making available of the invention by the applicant or by a person who obtained the relevant knowledge directly or indirectly from the applicant.

16.07 Ingenuity

As with every invention, in order to be patentable a computer-implemented invention must not be rendered obvious by prior art that is relevant under section 28.3 of the *Patent Act*.

Obviousness is evaluated in view of the overall state of the art contained in the prior art, when this is considered as a whole in light of the common general knowledge of the person skilled in the art. A claimed invention must be the result of ingenuity, and a conclusion of obviousness is equivalent to a conclusion of lack of inventive step. To be considered obvious, the teachings present in the prior art must be sufficient so that, if combined, they would lead to the claimed invention. Furthermore, it must be uninventive (obvious) to combine the necessary teachings.

As with the assessment of novelty, the assessment of obviousness is based on the essential elements of the claimed invention. There is nothing inventive in adding a non-essential element to an invention, since by definition the non-essential element is irrelevant to the invention's successful operation.

It is considered obvious that computers can be used to automate many manual operations, and the idea of automating a manual process is, in the absence of reasons to conclude the contrary, considered to be uninventive. The inventive step necessary to support a claim to a computer-automated version of a known manual method therefore must typically be found in the solution to specific challenges attendant to enabling the automation.

Where a computer-implemented invention aims to achieve a new unitary result through the use of a combination of known hardware and software, an inventive step may exist by virtue of the recognition that the combination will achieve that result. If, in contrast, using the hardware and software together merely results in a predictable outcome, the alleged invention is a mere aggregation.

16.08 Claims

A computer-implemented invention is typically claimed as a *machine*, a method (an *art* or *process*) or a *manufacture* (computer-readable medium). As with any type of claim, a claim to a computer-implemented invention must meet the requirements of, *inter alia*, subsection 27(4) of the *Patent Act* and section 84 of the *Patent Rules*.

16.08.01 Computer-implemented method claims

Where a claim is directed to a method that is to be implemented in whole or in part by computer, it must be unambiguously clear which steps of the method are being carried out by the computer.

Specifying in the preamble that a method is "computer-implemented" implies that some, but not necessarily all, steps of the method are performed by a computer. Where, in view of the specification as a whole, a given step can be understood as being performed either by a computer or by a person, it should generally not be presumed that the claimed method requires that step to be performed by a computer.

16.08.02 Computer claims

Where a claim is directed to a *machine*, it must be defined in terms of physical components.

Many computer claims will define the device in terms of means statements that set out what the device will do. Where a means statement is understood to be a software means, it must be specified that the software is stored on a physical memory. This can be done in the claim itself or in the description, with due regard being given to the need for the language of the claim to be clear, concise and unambiguous.

In some cases, it is possible that the means referred to in a means statement can be either hardware or software. In such cases, it may be most convenient to specify in the description that the means statement refers to either hardware or software on a physical memory.

16.08.03 System claims

The term *system*, depending on the context in which it is used, may refer to a *machine* (a device or apparatus, or a network of devices or apparatuses), a computer program or set of computer programs (e.g. a *database management system* or an *operating system*), or a *method*. Consequently, care must be taken to ensure that its intended meaning in a given context is unambiguous.

In the computer arts, where it is not clear that something else is meant it may be presumed that the term *system* refers to a *machine*.[11]

Regardless of which meaning is intended, it must be clear which category of *invention* the claimed subject-matter is meant to belong to. Where the claimed *system* is not a *machine*, it may be necessary to explicitly define that it is, for example, a software product or *method* in order to comply with subsection 27(4) of the *Patent Act*.

16.08.04 Software product claims

A computer program (software), when claimed *per se*, is considered by the Office to be an abstract scheme, plan or set of rules for operating a computer [see section 12.06.02 of this manual], and consequently not to be an invention within the meaning of section 2 of the *Patent Act*.

Under certain circumstances, software can be claimed by directing the claim to a physical memory storing the computer program. A claim to a physical memory falls within the category *manufacture*.

In defining a software product, the form of the claim is important. The preamble must clearly direct the claim to a physical product limited by the computer program stored thereon, and not to a computer program limited by having been stored on a memory. Thus, the preamble "a physical memory having stored thereon..." directs the claim to a statutory embodiment, whereas "a computer program stored on a physical memory" directs the claim to a computer program and thus to excluded subject-matter.

Furthermore, it must be explicitly defined that the computer program is present as machine-executable code. Only machine-executable code can change the technological functionality of the physical memory storing the program. Non-executable code is considered to be mere descriptive matter [see section 12.06.04 of this manual].

Where the computer program would cause the device it controls to provide a technological solution to a technological problem, the "software-modified physical memory" is a single discrete element. Where the program is novel and inventive, the claim will include a statutory contribution [see section 12.06.07 of this manual]. These, then, are the circumstances under which a software product comprising a physical memory storing executable code can be patented.

Example:

1. An application is directed to a computer-implemented method for determining a channel assignment in a Code Division Multiple Access (CDMA) network. The method improves CDMA networks by determining CDMA channel assignments according to predetermined constraints. It has been discovered that appropriate predetermined constraints improve efficiency in the network.

   The prior art search reveals that the following features were known from D1:
   - CDMA network with channel assignments
   - A computer-implemented method for performing the channel assignment

   D1 does not disclose the use of predetermined constraints to modify channel assignments

Claims:

1. A computer-implemented method for optimising channel assignments in a CDMA network, comprising the steps of:
a. performing an initial channel assignment;
b. comparing the channel assignment with predetermined constraints to determine a difference;
c. modifying said initial channel assignment in accordance with said difference; and
d. changing the channel assignment in the CDMA network in accordance with the modified channel assignment.

2. A computer program for optimising channel assignments in a CDMA network according to the method of claim 1.

3. A computer readable memory having recorded thereon statements and instructions for execution by a computer, said statements and instructions comprising:
a. code means for performing an initial channel assignment;
b. code means for comparing the channel assignment with predetermined constraints to determine a difference;
c. code means for modifying said initial channel assignment in accordance with said difference; and
d. code means for changing the channel assignment in the CDMA network in accordance with the modified channel assignment.

4. A computer program product comprising a computer readable memory storing computer executable instructions thereon that when executed by a computer perform the method steps of claim 1.

Analysis: Claim 1 defines a technological method comprising physical steps, and is therefore statutory in form. Assigning channels in a CDMA network according to the method results in an improved communications network; the method therefore provides a technological solution to a practical problem and the steps pertaining to the predetermined constraints are technologically distinct from similar steps performed without the constraints. The prior art does not disclose the feature of using predetermined constraints to modify an initial channel assignment in a CDMA network. Presuming that the examiner determines this to be an inventive feature, at least one physical step in the method will have been contributed. The claim would then include a statutory contribution and be allowable. Note that, to avoid indefiniteness, it would be necessary in an actual claim to define the actual “predetermined constraints” being relied on.

Claim 2 defines a computer program *per se* and is therefore directed to non-statutory subject matter by its form. The claim is objected to under section 2 of the *Patent Act*.

Claims 3 and 4 are alternative ways for defining a computer product. Both are acceptable in their form. To be patentable, the physical memory must be considered to be technologically distinct from other physical memories. This is considered to be the case where the computer program stored on the memory would cause a computer running the program to itself be a technological solution to a technological problem. A computer programmed in a novel way to implement the entirety of an inventive method is patentable in its own right [see section 12.06.06*b* of this manual]. Where the programmed device would be patentable, a physical memory storing the program as computer executable code is also patentable. Therefore, where the method of claim 1 would be patentable, either of claim 3 or claim 4 would also be allowable.

16.08.05 Means statements in claims

A "means" statement defines some part of an invention in terms of a *means* suitable for achieving a result, rather than by explicitly defining those specific things that would yield the result. Means statements are not objectionable *per se*, provided the claim meets all the requirements of the *Patent Act* and *Patent Rules*.

In order for a means statement to be properly supported, the description must describe what types of means are contemplated by the inventor unless this would be obvious to the person skilled in the art in view of their common general knowledge. Where it would not be obvious to the person skilled in the art which *means* fall within the scope of a defined means statement, the claim may be defective for lack of proper support or for indefiniteness. A *means* statement may refer to hardware or to software, and it should be clear in the context of the claim what the means statement refers to.

In the computer arts, the term "means" is often used in reference to a computer running software. Unless the context of the claim precludes this interpretation, a *means* statement that encompasses software may be understood to refer to software stored on a physical memory and being executed by a processor.

16.08.06 Mixed claim types

The subject-matter of a claim must belong to a category of invention as defined in section 2 of the *Patent Act*. The elements used to define the subject-matter must consequently be of a type appropriate to that category of invention.

Where a claim in one category of invention (e.g. a *machine*) defines its subject matter in terms of elements from another category (e.g. *method* steps), there is a risk of ambiguity over the intended subject-matter.

Where a claim is directed to a *machine*, it must define its subject-matter in terms of structural components whereby the machine can be distinguished from all other machines. Given that computers are often defined in terms of means statements that provide functional limitations to the machine, care must be taken to ensure these means statements can be understood to be physical components [see 16.08.02].[12]

Where a claim is directed to a *method* of using a device, it must include at least one step whereby the device is applied to the task at hand. A claim simply reading "*A method of using the device of claim 1.*" may be considered indefinite, for example, since the manner by which the device is used has not been defined.

Note that the "product-by-process" claim type defines a product wholly or partly in terms of the process by which it is produced. It is not a format for defining a product in terms of the method for which it will be used.

16.09 Special topics

This section addresses specific types of subject-matter for which particular attention, elaboration or clarification was considered appropriate.

In the following sections, the example claims are analysed following the approach set out in Chapter 13 [see, in particular, section 13.05 of this manual and its various subsections]. Furthermore, the analyses focus primarily on the question of whether a statutory contribution exists on the presumed facts of each example. In attempting to provide simplified examples, little consideration has been given to the question of enablement. Many of the example claims are defined in terms of broad functional statements ("means for" statements). In practice, whether these are properly supported would depend on the degree of disclosure and on the common general knowledge in the field [see section 16.05].

16.09.01 Graphical user interfaces

A "Graphical User Interface" (GUI), as the name implies, refers to a type of interface for enabling a user to interact with a computer or a computer-based device. While early computers used command line interfaces that required the user to enter textual commands to control a computer, graphical user interfaces enable the user to interact with the computer via visual elements such as icons, buttons, menus, toolbars and other graphical screen elements.

The term GUI is considered by the Office to refer only to the arrangement of visual elements that will be displayed on a screen, and not to include any of the hardware or software components that may be required to generate the graphical user interface or to make it functional. A GUI as such is consequently considered to be information, that when displayed on a screen is subject to the practice set out in section 12.06.04 of this manual.

An invention is considered to be a solution to a practical problem, which the Office considers to imply a "technological solution to a practical problem" [see section 13.05.01 of this manual]. Features having purely intellectual or aesthetic significance are not statutory subject matter and cannot provide a statutory contribution [see section 12.06.01 of this manual]. Any display of information wherein the sole contribution is in the information itself amounts to non-functional descriptive matter, and is not a patentable contribution [see section 12.06.04 of this manual].

The specific arrangement of graphical elements on a screen, or in other words the visual design that defines a graphical user interface, is viewed by the Office as not constituting a patentable contribution where the visual design of the graphical user interface does not provide a technological solution to a practical problem. Rather, it is viewed as having purely aesthetic significance and amounts to non-functional descriptive matter.

However, the presence of a graphical user interface does not exclude an invention from patentability if the criteria for patentability are satisfied. A GUI that has been integrated with statutory subject matter may be patentable. Claims including a GUI must be directed to one of the categories of invention, as defined in section 2 of the *Patent Act*.

Example 1:

An application discloses a portable device that allows a user to read an electronic book. The device comprises a touch screen, and displays the electronic book using an efficient graphical user interface that provides buttons for frequently used operations at the top of the screen, hyperlinks to other content within the book on the left of the screen, and a central frame for displaying the content of the book. The device also allows the user to enter personal notes at any location within the content of the electronic book. The personal notes are stored within XML tags that are embedded within the content, and a graphical icon is displayed at the location of each XML tag. The user is able to view stored personal notes by clicking on the relevant graphical icon. The touch screen is able to recognize advanced user touch commands, and the device comprises software to interpret such touch commands and perform specific functions.

The prior art search reveals that the following features are known from D1:

- displaying an electronic book on a portable device having a touch screen;
- displaying a graphical user interface including common elements such as hyperlinks, buttons, scrollbars, content frames and input boxes;
- the touch screen allows the user to point, click and drag items on the GUI.

The prior art does not disclose the efficient GUI arrangement of this application, the feature of storing personal notes using XML, or the feature of recognizing advanced touch commands.

Claims:

1. A graphical user interface for a portable electronic book reading device having a touch screen, the graphical user interface displaying on the touch screen:
- a series of buttons appearing at the top of the screen representing frequently performed operations;
- a region appearing at the left hand side of the screen containing a plurality of hyperlinks to other content within the electronic book;
- a scrollbar appearing at the right hand side of the screen;
- a central frame displaying a page of content from the electronic book;
- an input box appearing at the bottom of the screen for accepting user input.

2. A portable electronic book reading device having a touch screen displaying the GUI of claim 1.

3. A computer readable medium comprising computer instructions that when executed by a portable electronic book reading device having a touch screen displays the GUI of claim 1.

4. The computer readable medium of claim 3 further comprising instructions that when executed enable the portable electronic book reading device to:
- accept a text input from the input box representing a user's personal notes;
- identify a specific location within the page currently being displayed on the screen;
- embed the personal notes within the content of the electronic book at the identified location using predefined XML tags;
- parse the content of the electronic book to identify all embedded XML tags and to display a graphical icon at the location of each XML tag; and
- display the personal notes embedded within an XML tag upon user request.

5. The portable electronic book reading device of claim 2, wherein the touch screen is configured to recognize a pinching motion touch command by the user, and wherein the touch command enables the user to flip to the next or previous page of content by performing the touch command and dragging the page to the right or left hand side of the touch screen.

Analysis: Claim 1 defines a graphical user interface *per se* and is therefore directed to non-statutory subject matter by its form. The claim is objected to under section 2 of the *Patent Act*.

Claim 2, in contrast, is directed to a device and is therefore not objectionable in terms of its form. Upon closer examination, it is evident that claim 2 contains both statutory and non-statutory features. The portable device and the touch screen are two statutory features, while the arrangement of screen elements as defined in the claim is a non-statutory feature. The touch screen provides a technological limitation to the portable device, so the two are considered to be a single discrete element of the claim. However, the arrangement of screen elements does not provide a technological limitation to the portable device having a touch screen, and is therefore considered to be a second discrete element of the claim. In order to determine if the subject matter of claim 2 includes a statutory contribution, the prior art features disclosed in D1 must be compared to the statutory discrete element recited in the claim. Given that the prior art discloses a portable electronic book reading device having a touch screen, this feature does not form part of the contribution of the claim. It is not necessary to assess whether the arrangement of screen elements has been contributed, since it is a non-statutory discrete element and cannot itself result in a statutory invention. Following the contribution analysis, it is determined that claim 2 does not contain a statutory contribution. An objection under section 2 of the *Patent Act* on the basis of the non-statutory subject matter would be appropriate, since this matter is the point of the invention.

Claim 3 defines a computer program on a physical medium. The software allows the GUI of claim 1 to be displayed. The claim does not define any features that define a technological solution to a technological problem. The GUI of claim 1 remains a discrete element of the claim, and the physical memory comprising software that enables information to be displayed is a second discrete element of the claim. It is clear from D1 that software for displaying information was known in the prior art, and the memory having such software stored on it is therefore not part of the contribution. The claim can be objected to in the same manner as was claim 2.

Claim 4 is again directed to a computer program on a physical medium, but recites additional features allowing the user to embed personal notes at specific locations within the content of the electronic book using predefined XML tags, and to subsequently display the personal notes upon request. These features work together to modify the way in which the device executing the instructions stored on the computer readable medium operates, in such a way that they provide new functionality to solve a practical problem. In this case, the practical problem being how to enable the user to store and retrieve personal notes at specific locations within the content of an electronic book. Since the device itself would provide a technological solution to a technological problem and would be considered statutory, the computer readable medium storing the instructions that would control the device is also considered to be statutory [see 16.08.04]. If the examiner determines, based on the state of the art at the claim date, that the feature of embedding notes within the content of an electronic book using XML tags is novel and inventive, then this would be regarded as a statutory contribution and the claim would be allowable.

Claim 5 recites an additional feature of recognizing a specific touch command performed by the user of the touch screen, and performing a specific functionality based on such a touch command. Although the prior art touch screen allowed the user to point and click, it did not have the ability to recognize a complex motion such as a pinching motion similar to how a person would flip a page in a physical book. This feature is regarded as a technological feature providing new functionality to solve a practical problem, which is in this case to provide functionality to the touch screen to enable the user to conveniently browse through an electronic book using normal hand gestures. Since this feature is a technological modification to the portable electronic device, the overall modified device is now considered to be a single discrete element. If the examiner determines that this functionality is novel and inventive, a statutory contribution would be present in the claim and it would be allowable.

Example 2:

An application discloses a system for controlling the operation of network devices. Each device stores self-describing information detailing what type of device it is, and what control options are available to network users. A graphical user interface displays unique icons representing each device on the network, as well as a customized menu for each device showing available control options. The unique icon and the available control options are retrieved from each device on the network dynamically, resulting in a graphical user interface that accurately reflects the network at all times, even when changes are made to the network or the network devices.

The prior art search reveals that the following features were known from D1:

- A system for controlling network devices
- The system uses a GUI to display the devices and the available control operations

The GUI of D1 is static and does not obtain self-describing information from the devices.

Claims:

1. A graphical user interface generated by a computer program for facilitating the control of devices located on a network, comprising:
- a first graphical element representing each device located on the network; and
- a second graphical element representing available control options for each of the devices,
wherein the computer program dynamically retrieves the graphical representations and available control options from self-describing information stored within each of the devices.

> 2. A computer-implemented method for interacting with devices located on a network, comprising:
> - displaying a first graphical element representing each device located on the network;
> - displaying a second graphical element representing available control options for each of the devices; and
> - dynamically retrieving the graphical representations and available control options from self-describing information stored within each of the devices.

Analysis: Claim 1 is directed to a GUI, and further defines that the GUI is generated by a computer program and that program will dynamically retrieve certain information from devices attached to the computer. The claim is directed to excluded subject-matter by its form, however, and is objected to under section 2 of the *Patent Act*. The presence of the computer program feature indicates how the GUI is generated and modified, but the claim itself is still directed to a GUI *per se*.

Claim 2 is directed to a computer-implemented method wherein graphical elements are displayed and wherein the content of the display is dynamically updated by the computer program that generates the GUI. This method of controlling the operation of the computer provides a technological solution (dynamic querying) to the practical (technological) problem of having a current list of control options available for each peripheral device attached to the computer. The method enables the graphical user interface to be dynamically updated as devices on the network are added, removed or modified, and results in a more efficient system for controlling network devices. The method is statutory in form. Each step in the method includes both a statutory discrete element (displaying graphical elements or dynamically retrieving information) and a non-statutory discrete element (the information that is displayed or retrieved, and which does not limit the technological aspects of displaying or retrieving). The statutory steps of displaying graphical elements and dynamically retrieving information from the peripheral devices would be examined to determine if the overall method is both novel and inventive over the prior art. Since the steps operate together to provide a unitary result, they are compared to the prior art in combination.

Note that if the method is considered to be novel and inventive, a claim to a device operating the method or to a physical memory storing the software that enables the method would also be allowable.

16.09.02 Data structures

A data structure is a format for organizing and storing a collection of related data items to suit a specific purpose. A particular data structure may enable or facilitate a specific set of operations to be performed on the data items easily and efficiently, for example to improve the performance of computer programs and minimize the consumption of computer resources. Examples of data structures are arrays, records, linked lists, stacks and trees.

The Office considers a data structure to be an abstract idea or plan for organizing data items, and not to include the physical medium upon which the data structure is to be stored. A data structure *per se* is consequently considered to be disembodied and not an invention within the meaning of section 2 of the *Patent Act* [see section 12.06.02 of this manual]. For a data structure to have an impact on the patentability of a claimed invention, it must in some way limit the technological nature of a statutory element in the claim.

Example:

An application discloses a networking system that guarantees a quality of service for a networking connection, wherein the system comprises networking equipment that is used to transmit data packets across a network. The data packets include a quality of service indicator that is read by other networking equipment along the path of the transmission, such that the networking equipment will prioritize delivery of packets with a higher quality of service guarantee.

The prior art search reveals that the following features are known from D1:

- Networking equipment for transporting data packets from source to destination
- Data packets having a header and a payload for transporting data through a network
- Packet header containing control bits including addresses and error correction bits

The prior art does not disclose prioritizing packet delivery based on a quality of service indicator within the packet header.

Claims:

1. A data structure for transmitting data over a network with a guaranteed transmission quality of service, the data structure being a packet comprising:
- a payload containing the data to be transmitted;
- a header containing control bits for managing the transmission of the data, including:
    - a source address indicating the source of the data;
    - a destination address indicating the destination of the data;
    - error detection and correction bits;
    - an 8-bit quality of service indicator that is used by networking equipment to prioritize delivery of packets.

2. A memory for storing data for access by an application program being

executed on a data processing system, the memory storing the data structure of claim 1.

3. A computer-implemented method for data transmission with a guaranteed quality of service comprising:

a) transmitting and receiving data over a network using data packets according to claim 1; and
b) prioritizing the delivery of data packets on the basis of the quality of service indicator.

Analysis: Claim 1 defines a data structure *per se*, and is therefore directed to non-statutory subject matter by its form.

Claim 2, in contrast, is directed in form to a physical memory, and consequently to a statutory *manufacture*. The data stored on the memory does not alter the technological character of the memory, and therefore is a discrete element of the claim. The claim, consequently does not include a statutory contribution. Since the data structure is the point of the invention, an objection could be presented under section 2 of the *Patent Act* on the basis of a contribution analysis. Note that the conclusion differs from that which could be reached if the physical memory were storing executable computer code that made use of the structure to render a computer more efficient or reliable.

Claim 3 defines a method for transmitting and receiving data wherein the system can prioritize data based on its quality of service indicator. The data structure is made use of to control the manner by which data packets are transmitted, and this changes the technological character of step b). The step of prioritizing delivery is understood to involve an analysis of the packets, an evaluation of network traffic and available bandwidth, possibly storing certain packets temporarily, etc. Depending upon the state of the art and the common general knowledge in the field, such details might need to be defined in an actual claim. Both steps in the method are technological in nature, and the method provides a technological solution to a practical problem and is statutory. If the data structure and its technological effect are found to be novel and inventive, the method would be patentable.

16.09.03 Databases

In general terms, a database refers to a collection of information organized so that it can be stored, searched and retrieved easily. Computer databases can be implemented in many forms, the simplest being to store information in a text file in a specific format (a data structure) to enable the information to be subsequently retrieved. More advanced implementations employ specialized software, often referred to as a *database management system*, to control access to the stored information. Examples of common *database management systems* in use today include Microsoft™ Access™, MySQL™, and Oracle™.

The Office interprets a database to be solely a collection of information, and not to include the physical medium upon which the database is stored. A database *per se* is consequently considered to be disembodied and not an invention within the meaning of section 2 of the *Patent Act* [see section 12.06.02 of this manual]. Where a database, as a feature of a claim, limits the technological nature of a statutory element in the claim it can result in a statutory contribution.

A *database management system* is generally understood in the art to be a computer program [see 16.08.03 on *system* claims]. A claim to a *database management system* computer program is not directed to a statutory invention whereas a claim to a physical memory storing a *database management system* defines, in form, a statutory *manufacture* [see 16.08.04].

Example:

An application discloses a distributed database system to reduce the load on database servers in a network. The same database is stored on multiple database servers. A common control server receives database access requests and distributes them among the multiple database servers. The control server keeps track of the load on each database server, and distributes requests in order to evenly distribute the load on the servers. The control server also periodically synchronises the data across the database servers during periods of lighter load, in order to maximise performance of the overall distributed database system. The application describes the use of the distributed database system for a web based social networking application.

The prior art search reveals that the following features are known from document D1:

- a web application using a distributed database system,
- that database access requests are distributed across the system, and
- that synchronisation is performed at set intervals

The prior art does not disclose the feature of a common control server keeping track of the load on the database servers in order to evenly distribute access requests and scheduling database synchronisation during periods of light server load, which results in improved performance of the overall distributed database system.

Claims:

1. A distributed database system comprising:
i) a plurality of database servers, each of which stores a copy of a database;
ii) a control server for controlling the distributed database system, wherein the control server comprises:
a) means for distributing received database access requests among the

plurality of database servers; and
b) means for performing database synchronisation to synchronise the content of the databases stored on the database servers.

2. The system of claim 1, further comprising:
iii) a web-based social networking application server;
wherein the distributed database is used to store for each user of the application:
- account information;
- profile information;
- a list of relationships between users; and
- messages sent and received by each user.

3. The system of claim 2, wherein the control server further comprises:
c) means for tracking the load of each of the plurality of database servers;
wherein the database access requests are distributed among the plurality of database servers according to the load of each server in order to evenly distribute the load among the database servers;
and wherein the database synchronisation is performed during periods where the database servers are experiencing a lighter than normal load.

4. A database comprising data related to a web-based social networking application, wherein the database includes for each user:
- account information;
- profile information;
- a list of relationships between users; and
- messages sent and received by each user.

Analysis: Claim 1 defines a plurality of servers i), wherein each server stores a copy of the database, and a control server ii) which comprises means to manage the system as a whole. The means statements are understood to be software stored on a physical memory and executed by the server's processor. The means both alter the technological operation of the control server ii), and the "software on a physical memory" means are therefore statutory elements of the claim. Equivalently, the "means-modified control server" may be considered a single discrete element of the claim. Each server i) is also a discrete element of the claim, as is the database (which does not provide a technological limitation to the server storing it). The patentability of the claim will depend on whether server ii) is found to be novel and inventive, since the servers i) are known and since the database is not a statutory feature of the claim. In view of D1, the server ii) would be considered novel. For the sake of this example, it is presumed that the server is found to be obvious in view of the cited prior art and knowledge in the field. The claim would therefore be objected to under section 28.3 of the *Patent Act*.

Claim 2 adds to the features of claim 1 a web-based social network application server, and defines the information stored for each user of the system. The application server is a statutory feature. In this example claim, there is insufficient information defined about the nature of any software on the server (i.e. how the social network application works) to determine whether the software would enable the server to solve a particular technological problem. In view of D1, which discloses a web-based application, it does not appear that the server iii) distinguishes the system over the prior art. The further feature of the claim, the specific information stored, is a non-statutory feature which does not provide a technological limitation to the server. The data is therefore a discrete element of the claim. To the extent it appears the applicant is asserting the data in order to distinguish the invention, an objection under section 2 of the *Patent Act*, referring to a contribution analysis, is warranted.

Claim 3 adds to claim 2 the additional feature of the system comprising means for tracking the load of the database servers, distributing database access requests according to this information in order to evenly distribute the load on the servers, and performing synchronization during periods of lighter than normal load. This means is, again, understood to be software stored on a physical memory and being executed by a processor. The means provides new technological functionality to the control server, and is a statutory "software on a physical memory" element of the claim. Equivalently, the means-modified server can be considered to be a single discrete element of the claim. If the examiner considers that the server having a means to provide the defined functionality is novel and inventive over the prior art, claim 3 would be considered to involve a statutory contribution and would be allowable.

Claim 4 defines a database *per se*, and is therefore directed to non-statutory subject matter by its form. The examiner will object to this claim under section 2 of the *Patent Act*.

16.09.04 Computer-aided design (CAD) programs

A computer-aided design program is a computer program specifically used in the design of objects and to perform simulations on designed objects before the final product is actually built, thereby leading to significant reductions in time and cost. CAD programs are used in many industries including architecture, automotive, electronics and computer animation among others.

CAD programs are typically not capable of independently performing the act of designing; rather they are tools that are used by designers to help with the design process. Inventions related to CAD programs will therefore usually focus on the functionality of the CAD program as a tool used to assist the designer, and not on their ability to independently carry out a design. While methods of designing may be viewed as schemes or mental processes, which are disembodied and not a practical form of an invention, CAD programs are tools that are used during the design process and may comprise a technological contribution.

A CAD program is a specialized type of computer program, and consequently the practices pertaining to computer programs apply to CAD programs.

Example 1:

An application discloses a computer-aided design tool for automatically performing integrated circuit placement, layout and routing. The tool starts its process by reading a netlist file defining all the components in a circuit schematic and their interconnections. The CAD program then performs the circuit placement, layout and routing using a hierarchical approach wherein simple circuit cells (sub-circuits within the overall circuit) are optimised first (this being the lowest level in the hierarchy), then larger sub-circuits (second and subsequent levels in the hierarchy), and so on until the overall circuit has been created. The program first scans the circuit to look for circuit cells, optimizes one example of each such cell and adjusts all others according to the optimized result. It then scans the circuit looking for larger cells and repeats the process until the overall circuit has been optimized. Since each higher level is optimised relying on the results of the lower level optimisation, fewer operations are needed overall in order to optimise the overall circuit. The approach also avoids "false minimum" optimisation results that can occur when the starting point of the optimisation is too unrelated to the actual optimised circuit. The optimised circuit can be displayed as an image, schematic, or as a control file for a computer-controlled fabrication process.

The prior art search reveals that the following features are known from D1:

- a CAD program for automated layout and routing requiring the manual placement by a user of all circuit cells before routing can be performed;
- a series of calculations that optimise the entire circuit iteratively.

The prior art does not disclose using a hierarchical approach to perform the layout and routing.

Claims:

1. A computer-implemented method for the automated optimisation of an integrated circuit design, comprising:

- reading a netlist file defining all circuit elements and interconnections;
- identifying circuit cells that are repeatedly instantiated in the design;
- creating a tree representation of the circuit cells and their hierarchical relationship;
- starting at the lowest level of the hierarchy:
    a) performing integrated circuit layout of the individual circuit cells;
    b) identifying the interconnections between the circuit cells;

c) performing placement and routing of the circuit cells while minimizing interconnection length and routing complexity;

- repeating steps a - c for all remaining levels within the hierarchy of the circuit, proceeding from the next lowest level to the highest level; and
- generating an output file containing the detailed layout and routing of the integrated circuit.

2. A computer-aided design program for performing the method of claim 1.

3. A computer readable memory having recorded thereon statements and instructions for execution by a computer to carry out the method of claim 1.

Analysis: Claim 1 defines a computer-implemented method whose object is the solution of a technological problem - how to provide an optimised layout of a circuit based on predetermined input parameters while avoiding "false minimum" results and minimising the number of operations necessary to optimise the circuit. The method as a whole therefore is statutory in its form. Each step in the method involves a series of computer operations for performing a specific task. The steps of reading the netlist file and generating an output file can be treated as discrete elements, since they do not limit the technological nature of the remaining steps. They represent known computer operations and are presumably not part of the contribution.

For this example, it is presumed that the hierarchical approach to optimising the circuit was not previously known and would not be obvious. The method provides a technological solution to a practical problem in the operation of the computer: it requires fewer computer operations to arrive at the optimised circuit than the prior art method, and in effect allows the computer to perform the optimisation more accurately and efficiently. The steps in the method relating to how the computer performs the analysis are therefore a statutory contribution, and the claim is consequently patentable.

Note that the question of *how* the hierarchical analysis and optimisation is performed is essential to the claimed invention; it is worth reiterating, in respect of this example in particular, that depending on the extent of the description and the state of the common general knowledge, specific details regarding the implementation of the method may be required in the claim.

Note that if the hierarchical approach had already been known, the analysis would be different. In that case, a contributed technological solution to a technological problem would only exist if a specific obstacle to implementing the steps relating to the hierarchical approach in a computer had been overcome. In such a case, the specific inventive operations to be performed by the computer to provide this solution would need to be specified.

Claim 2 is directed to a computer program *per se*, and is defective in form.

Claim 3, in contrast, illustrates a claim properly directed to a computer product. Given that the method of claim 1 is patentable, a computer implementing the entire method also would be patentable. The subiect-matter of claim 3, a physical memory embodying a computer program that would render a computer running it patentable, is likewise patentable.

Example 2:

An application discloses a CAD program for optimizing transistor sizing for combinatorial networks. The program uses the Logical Effort gate delay model to optimize transistor sizing based on gate load and the desired delay characteristics. The program takes as inputs a schematic netlist file and the desired delay through the critical path of the circuit. The program calculates the optimum width and length for each transistor in the critical path of the circuit, and produces an output netlist file with that information.

The prior art search reveals that the following features are known from D1:

- The Logical Effort gate delay model and associated equations are known
- Using the Logical Effort gate delay model to optimize transistor sizing is known

The prior art does not disclose using a computer program to automatically optimize transistor sizing based on Logical Effort, taking as inputs only the netlist and the desired delay.

Claims:

1. A computer-implemented method for optimising the transistor sizing of a circuit schematic, comprising the steps of:
- reading a netlist file defining all circuit elements and interconnections;
- reading an input defining the desired delay of the critical path of the circuit;
- identifying the critical path of the circuit;
- identifying the fanout of each gate along the critical path;
- calculating optimum transistor sizing for each gate along the critical path using the Logical Effort gate delay model, so as to provide the desired delay; and
- generating an output netlist file having the optimum transistor sizing.

Analysis: Claim 1 defines a method for using a computer to optimise a circuit schematic. The claim is statutory in its form. The steps of reading a netlist file and generating an output netlist file can each be considered a discrete statutory element of the method, and it is understood that neither forms part of the contribution.

The remaining steps relate to a series of calculations. It is presumed for the purposes of this example that the description does not disclose any obstacles that were encountered in implementing the calculations on the computer. The sequence of operations necessary to perform the calculations would have been self-evident to a person skilled in the art presented with the equation. Consequently, there was no technological innovation in enabling the computer to perform the calculations. The steps of calculating are consequently simply the performing of an otherwise non-statutory method of calculation on a computer. Absent a technological problem to be overcome in how the computer performs the calculations, there is no statutory contribution in the claimed matter. Given that the specification emphasises the importance of the specific calculations, it would be appropriate to object to the claim under section 2 of the *Patent Act* in light of a contribution analysis.

16.09.05 Signals

The Office regards electromagnetic and acoustic signals and waveforms to be forms of energy and not to contain matter despite that the signal may be transmitted through a physical medium. As a result, claims to electromagnetic and acoustic signals do not constitute statutory subject-matter within the definition of *invention* in section 2 of the *Patent Act*.

More particularly, an electromagnetic or acoustic signal is interpreted to be neither an *art* nor a *process* because it is not an act or series of acts or method of operation by which a result or effect is produced by physical or chemical action. Neither is an electromagnetic or acoustic signal a *machine*, as it is not the mechanical embodiment of any function or mode of operation designed to accomplish a particular effect, or a *composition of matter*, as it is not a chemical compound, composition or substance. An electromagnetic or acoustic signal is considered not to be a material product and, therefore, not a *manufacture*.[13]

The Office considers signals to be transitory in nature, and to exist only while being propagated.[14] Once the information contained in a signal has been stored on a physical medium, it is no longer considered to be a signal and is more appropriately referred to as data. Therefore, claims that define a physical medium storing a signal or a waveform are considered indefinite under section 27(4) of the *Patent Act*.

Although signals *per se* are not patentable, methods, processes, machines or manufactures involved in the generation, transmission, reception, or processing of signals may be patentable if all other criteria for patentability are satisfied.

Example:

An application discloses a transmission system to transmit video data over short distances. The system uses a carrierless ultra wideband signal, where the video data is encoded into multi-phase wavelets. The system allows for transmission at high data rates over short distances, and can be used to transmit video from a security camera to a recording device, for example. When transmitted at low power, such carrierless transmissions do not interfere with narrowband or spread spectrum signals.

The prior art search reveals that the following features are known from D1:

- Wireless security system including security video cameras
- Wireless transmission of video data over short distances

D1 does not disclose the use of a carrierless ultra wideband signal where the data is encoded into multi-phase wavelets.

Claims:

1. A data signal for transmission of video data over short distances, the signal being embodied in a carrierless ultra wideband waveform wherein the data is encoded into multi-phase wavelets, the signal being transmitted from a transmitting antenna to a receiving antenna.

2. A physical transmission medium carrying the signal of claim 1.

3. A transceiver for transmitting and receiving data signals comprising:
- means for encoding video data into multi-phase wavelets;
- means for transmitting the encoded data as a data signal embodied in a carrierless ultra wideband waveform; and
- means for receiving and decoding the transmitted signal to retrieve the original video data.

Analysis: Claim 1 defines a signal *per se*, and is therefore directed to non-statutory subject-matter by its form and is objected to under section 2 of the *Patent Act*.

Claim 2 defines a physical transmission medium and is therefore directed in form to statutory subject-matter. The signal does not provide any technological limitation to the transmission medium, however, and the claim therefore includes two discrete elements (the medium and the signal). Since the physical transmission medium has self-evidently not been contributed, the claim does not include a statutory contribution. As the signal of claim 1 appears to be the inventive aspect, an objection is made under section 2 of the *Patent Act* in light of the contribution analysis.

Claim 3 defines, in form, a statutory device. The claim recites means for encoding, transmitting, and receiving and decoding data signals. For the purposes of this example, it is presumed that it is clear from the description that certain of the means relate to hardware components and others to software stored on a physical memory. The encoding of the data into multi-phase wavelets allows the transceiver to transmit data at a high rate while minimizing interference with other signals. Thus, the technological character of the device is modified by the software-enabled encoding. The claim does not include a discrete non-statutory element, and the patentability of the claim is evaluated on the basis of the novelty and ingenuity of all the defined elements in combination. Presuming the use of multi-phase wavelets is considered novel and inventive, the claim would be allowable.

Endnotes for chapter 16

1. Source code for computer programs may, however, be subject to the protection of the *Copyright Act* as a literary work.

2. *Schlumberger Canada Ltd. v. Commissioner of Patents* [(1981), 56 C.P.R. (2nd), 204 (F.C.A.)] at page 206

3. *i.e.* provide a technological solution to a technological problem

4. *Re Application for Patent Containing Claims that Read on Mental Steps* [(1972), 23 C.P.R. (2nd), 93] ; *Re Application 269,230 of Itek Corporation* (1981) C.D. 896

5. *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.* [(2002), 17 C.P.R. (4th), 478 (F.C.A.)] at paragraphs [35] and [42]

6. *Bauer Hockey Corp. v. Easton Sports Canada Inc.* 2010 FC 361 at paragraphs [216] to [220]

7. *Bauer* (supra at 6) citing *Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co. Ltd.* (1995), [1996] R.P.C. 76 (H.L.) at p. 86

8. *Bauer* (supra at 6) citing *Lux Traffic Controls Limited v. Pike Signals Limited*, [1993] R.P.C. 107 (Pat. Ct.) at p.132

9. *Baker Petrolite* (supra at 5) at paragraph [42]

10. *Baker Petrolite* (supra at 5) at paragraph [42]

11. see, e.g., the comments in *Re Application 2,349,479 of U-Haul International Inc.* (2010) C.D. 1298 at paragraphs [37] to [42]

12. *Re Application of U-Haul* (supra at 11) at paragraphs [37] to [42]

13. *Office Practice Regarding Signals* C.P.O.R. Vol. 135, No. 33, August 14, 2007

14. A signal is considered to be propagating even if it is moving in a closed loop.

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Chapter 17
Biotechnology

17.01 Scope of this chapter

The purpose of this chapter is to highlight Office practice particularly as it pertains to applications concerning those diverse fields of research generically referred to as "biotechnology". In reading this chapter, it should be borne in mind that its purpose is to clarify, through elaboration, the application of the more generic teachings of other chapters to the particular issues encountered in biotechnology inventions.

Nothing in this chapter should be interpreted as providing exceptions to any practice of general applicability set out in any other chapter.

As a matter of administrative economy, certain principles of general applicability are, however, discussed in the present chapter. Inclusion of these sections (e.g. on utility, sufficiency, selection patents, etc.) is intended to clarify practice in these areas of particular importance to biotechnology prior to formal amendment of the relevant chapters to which they more appropriately belong.

Throughout this chapter the term "biomolecule" has been used, as a matter of convenience, to collectively describe nucleic acids, peptides, polypeptides, and proteins.

17.02 Subject-matter

As with every invention, in order to have standing under the *Patent Act* the matter of a biotechnology invention must fall within one of the five categories found within the section 2 definition of "invention", namely art, process, machine, manufacture, and composition of matter. Biotechnology is notable, however, in the number of jurisprudential interpretations whereby certain types of matter have been found not to fall within the scope of section 2.

This section discusses the relationship of several types of biotechnology to section 2 of the *Patent Act*.

17.02.01 Living matter

17.02.01*a* Higher and lower life forms

For the purposes of section 2 of the *Patent Act*, life forms have in view of jurisprudence been divided into lower life forms (statutory) and higher life forms (non-statutory).

In Commissioner's Decision *Re Application of Abitibi Co.* it was determined that life forms which are produced *en masse* as chemical compounds are prepared, in such large numbers that any measurable quantity will possess uniform properties and characteristics, are generally deemed to fall within the scope of section 2 as being either "manufactures" or "compositions of matter".[1]

In contrast, the Supreme Court ruled in *Harvard College v. Canada (Commissioner of Patents)* that higher life forms do not fall within the scope of section 2.[2]

The Patent Office considers the distinction between lower and higher life forms to be, in general, whether the life form is unicellular (lower) or multicellular (higher). The *Harvard* decision is interpreted by the Patent Office to mean that animals at any stage of development are not statutory matter for letters patent, and consequently that fertilized eggs and totipotent stem cells (which have the inherent ability to develop into animals) are included in the higher life form proscription.[3]

Embryonic, multipotent and pluripotent stem cells, which do not have the inherent ability to develop into an animal, are considered to be lower life forms. Where a claim to a cell could be reasonably understood in view of the description as encompassing within its scope a fertilized egg or totipotent stem cell, this matter should be expressly excluded by proviso to avoid a section 2 "higher life form" rejection.

Note that the fact that a claimed cell could form part of a higher life form does not mean that the claim to the cell should be equated to a claim to the higher life form. There is no need for a claim to a statutory cell to specify, in order to avoid a "higher life form" rejection, that the cell is "as found in the laboratory" or is "in isolated form".[4]

Lower life forms include: microscopic algae; unicellular fungi (including moulds and yeasts); bacteria; protozoa; viruses; transformed cell lines; hybridomas; and embryonic, pluripotent and multipotent stem cells.

Higher life forms include: animals, plants, seeds, mushrooms, fertilized eggs and totipotent stem cells.

Plant varieties that are distinct, uniform and stable may be protected under the *Plant*

Breeders' Rights Act, administered by the Canadian Food Inspection Agency.

Examples:

1. A bacterial cell culture deposited as ATCC 1234.
(statutory)

2. A hematopoietic stem cell derived from bone marrow, capable of giving rise to erythrocytes, neutrophils, granulocytes, lymphocytes or platelets, said cell bearing surface markers W, X and Y and obtained by a selective separation method using monoclonal antibody Z.
(statutory)

3. A plant transformed with an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1.
(non-statutory)

4. A plant cell transformed with an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1.
(statutory)

5. A plant propagation material produced by transformation of a plant cell with an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1.
(non-statutory)

6. A fertilized bovine ovum carrying an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1.
(non-statutory)

7. A cell transformed with an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1 provided said cell is not a fertilized egg cell or a totipotent stem cell.
(statutory)

Analysis: Examples 1, 2, and 4 are directed to cells that do not fall into the proscribed categories of fertilized eggs and totipotent stem cells. In contrast, examples 3, 5 and 6 are directed to proscribed higher life forms. In the case of example 5, this is because a “plant propagation material” includes seeds, plant cuttings, rhizomes and tubers of tuber-bearing plants. Example 7 is intended to reflect the situation where, in view of the description, it is clear that the cells of the invention include fertilized eggs and totipotent stem cells. To avoid a section 2 rejection, these non-statutory embodiments have been expressly excluded by proviso.

17.02.01*b* Organs and tissues

Organs and tissues (whether of plant or animal origin) are generally not considered to be manufactures or compositions of matter for the purposes of section 2 of the *Patent Act*. Organs and tissues are in general created by complex processes, elements of which require no technical intervention, and do not consist of ingredients or substances that have been combined or mixed together.

Artificial organ-like or tissue-like structures, generated by technical intervention by combining various cellular and/or inert components, may be considered, on a case-by-case basis, to be manufactures or compositions of matter and therefore to be statutory subject-matter.

Examples:

1. A heart isolated from a pig and suitable for transplantation into a human, said pig heart being genetically engineered to express human cell surface antigens.
(non-statutory)

2. An artificial heart valve comprising polymeric scaffold material configured in the shape of a human heart valve, said scaffold material seeded with human myocytes derived from a human myogenic stem cell line.
(statutory)

3. Plant tissue genetically altered to express SEQ ID NO: 1.
(non-statutory)

17.02.02 Processes to produce life forms

The patentability of a method or process is independent of whether or not the product of the method or process is statutory. Processes to produce higher life forms, organs or tissues are not, therefore, objectionable on the grounds that they produce non-statutory products.

An especially important consideration in biotechnology, however, is the degree of technical intervention embodied in the claimed process. A process which occurs essentially according to nature, with no significant technical intervention by man, is not patentable.[5] Thus, for example, a process for producing a plant by traditional cross-breeding techniques is not patentable.

Processes which are considered to include significant technical intervention by man include: processes to produce a lower life form, a higher life form, an organ or a tissue through genetic transformation; processes for the *in vitro* culturing or manipulation of cells; processes to separate cells; and processes to generate mutants using a chemical or physical agent.

Examples:

1. A process to produce an insect resistant plant, comprising:
    (i) transforming a plant cell with an expression vector carrying a nucleic acid sequence encoding a protease inhibitor; and
    (ii) regenerating a plant from said transformed cell.
(acceptable)

2. A process for producing a tomato plant with reduced stature, comprising:
    (i) crossing tomato variety A with tomato variety B;
    (ii) selecting progeny of said cross that have reduced stature; and
    (iii) backcrossing the selected progeny with tomato variety A.
(not acceptable)

3. A process for producing artificial skin, comprising:
    (i) providing a perforated biocompatible membrane;
    (ii) seeding said membrane with epithelial cells; and
    (iii) cultivating said cells thereon *in vitro*.
(acceptable)

17.02.03 Medical and surgical methods

As mentioned in section 12.04.02, a method which provides a practical therapeutic benefit to a subject, even if this is not its primary or intended purpose, is considered to be a method of medical treatment and is therefore not patentable.[6] By way of examples, surgical, medical, dental and physiotherapeutic methods of treatment are non-statutory matter.

To be considered a method of medical treatment, the method should cure, prevent or ameliorate an ailment or pathological condition, or treat a physical abnormality or deformity such as by physiotherapy or surgery. Certain natural conditions such as ageing, pregnancy, baldness and wrinkles are not considered to be pathological, and methods to treat such conditions are therefore not proscribed.

Methods that involve performing surgery on the human or animal body are excluded, whether the effect of the surgery is therapeutic or not. Methods that involve the excision of tissue, organ, or tumour samples from the body are considered to be forms of surgery, and are excluded regardless of their reproducibility. The removal of fluids from the body such as by needle or cannula is not of itself surgery.[7] A method to remove fluids may nevertheless be proscribed if it otherwise involves surgery, such as in the placement of a cannula or stent in the body,[8] or if it lacks utility, e.g. for not being reproducible.

Claims which do not involve a step of surgery or provide a practical therapeutic benefit do not form part of the method of surgery or medical treatment exclusion.[9] Thus, certain methods of diagnosing a disease or medical condition, whether practised *in vitro* or *in vivo*,[10] of treating an animal solely to derive an economic benefit,[11] or for achieving a cosmetic result may be patentable.

As mentioned in section 11.10.02, use claims are permitted but are scrutinized closely to ensure they do not equate to a medical or surgical method, for example by the inclusion of a medical or surgical step.

Similarly, a claim which recites a dosage regime, or a prescribed dosage amount, may be directed to a method of medical treatment since dosage regimes and prescribed dosage amounts fall within the purview of a medical professional.[12] However, dosage forms, pharmaceutical packages or kits, which may physically embody a dosage regime or prescribed dosage amount, are considered patentable subject matter.[13]

The removal of the medical aspect of a claim may render it acceptable. Inclusion of terms such as “cosmetic”, “diagnostic” or “non-medical” in a claim may be taken as disclaimers to medical methods provided the description contains adequate support for such terminology and provided the claim can reasonably be understood to be directed to a non-medical method the results of which cannot reasonably be said to produce a practical therapeutic effect.

Examples:

> 1. A method of preventing cervical cancer in a human subject, comprising administering a human papilloma virus peptide defined by SEQ ID NO: 1 to said subject.

Analysis: non-statutory, since the method is self-evidently a method of medical treatment.

> 2. A method of producing antibodies specific for the human papilloma virus peptide defined by SEQ ID NO: 1, comprising administering said peptide to a rodent.

Analysis: statutory, since rodents are not susceptible to human papilloma virus and do not derive any therapeutic benefit from the administration of the peptide.

> 3. A method of producing tenderized meat, comprising:
>
> (i) injecting an animal with a proteolytic composition; and
> (ii) slaughtering said animal after a period of time sufficient to allow for tenderization of the meat of said animal.

Analysis: statutory, since the animals do not obtain any therapeutic benefit from the method, and the method has clear industrial applicability.

> 4. A method for detecting and localizing a breast tumour, without medically treating said tumour, which method comprises the following steps:
>
> (i) injecting a subject with an antibody X which has been labelled with a diagnostically effective amount of a radioactive isotope;
> (ii) allowing said labelled antibody to localize at the site of the breast tumour; and
> (iii) detecting the emission of radioactivity from said radioactive isotope thereby localizing the site of the breast tumour in said subject.

Analysis: Statutory because, in this case, there is a distinction between the concentration of the radioisotope-labelled antibody which is used for diagnosis and that which would provide a therapeutic effect. The proviso "without medically treating said tumour" therefore qualifies the amount of antibody used and restricts it to non-therapeutic concentrations.[14]

> 5. A method of analyzing a sample of breast tissue to diagnose breast cancer in a subject, comprising the following steps:
>
> (i) homogenizing said sample in extraction buffer to yield soluble and insoluble fractions;
> (ii) separating the soluble fraction from the insoluble fraction;
> (iii) reacting the soluble fraction with [novel] antibody X; and
> (iv) detecting specific binding of antibody X with antigen Y
> wherein specific binding of antibody X to antigen Y indicates the presence of breast cancer.

Analysis: Statutory, since the method is clearly a diagnostic method and has been drafted in such a manner that any acts required to obtain the necessary sample of breast tissue do not form part of the claimed invention.

> 6. A method of detecting breast cancer in a subject comprising the following steps:

(i) obtaining a sample of breast tissue from a subject by [novel] needle biopsy conducted under the virtual guidance of a system which generates a three-dimensional image of a putative breast tumour which has been localized *in vivo* by immuno-radiography with an antibody reactive with antigen Y; and
(ii) detecting the presence of antigen Y in said sample,
wherein the presence of antigen Y at an amount exceeding 125 ng/g of tissue indicates the presence of breast cancer.

Analysis: non-statutory, since step (i) involves a step (a needle biopsy) which equates to surgery.

7. A method of screening for a potential drug for [human] disease X, comprising:
    (i) administering a plurality of test compounds to [novel] mice which have been genetically engineered by insertion of human gene Y to mimic disease X;
    (ii) evaluating the severity of disease progression in said mice in the presence and absence of each of the compounds; and
    (iii) selecting compounds which slow disease progression as potentials for treating disease X.

Analysis: statutory, since a method wherein a disease is induced in an otherwise healthy subject is not a method of medical treatment, even if the so-induced disease is subsequently treated.

17.02.04 Bioinformatics

Biomolecules are chemical compounds, and claims to nucleic acids, polypeptides, proteins and peptides are therefore directed to statutory matter. Certain biomolecules, further, express information through their primary structure (i.e. their sequence).

The three-dimensional structure of a biomolecule is often of importance in understanding its biological activity and behaviour. A claim to a biomolecule, defining the molecule in terms of its atomic coordinates, is statutory. In contrast, a claim to the three-dimensional atomic coordinates that represent the shape of the biomolecule in space is not statutory. The coordinates themselves are simply information, which is non-statutory.

Note that the exclusion from patentability of information does not depend on whether or not the information has been recorded on a carrier, nor on the nature of the carrier.

A computer model of a biomolecule which relies on the structural information of the biomolecule is not patentable, since the model itself equates to a graphical presentation of the underlying information. This exclusion extends to include generic computer systems and/or programs that have merely been configured to generate the model.

Computer models of biomolecules can be used in, for example, *in silico* screening methods. The mere presence of a computer model of a biomolecule in a method does not of itself render the method unpatentable.

Examples:

1. A polypeptide comprising the amino acid sequence depicted in SEQ ID NO: 1.
(statutory)

2. A protein comprising the atomic coordinates set out in figure 1.
(statutory)

3. A computer readable medium having recorded thereon the sequence set forth in SEQ ID NO: 1.
(not acceptable)

4. Atomic coordinates of protein X, said coordinates depicted in figure 1.
(non-statutory)

5. A method of obtaining inhibitors of protein X, comprising the steps of:
    (i) generating a three-dimensional computer model of protein X using the atomic coordinates depicted in figure 1;
    (ii) identifying the binding site of protein X using said model; and
    (iii) electronically screening a library of compounds with defined spatial coordinates in order to identify compounds which are structurally complementary to the binding site of protein X; and
    (iv) preparing complementary compounds as inhibitors of protein X.
(statutory)

17.03 Utility

Presuming that the claims define statutory subject-matter, section 2 of the *Patent Act* also requires that the matter of an invention be useful. As noted in *Consolboard v. MacMillan Bloedel*, a lack of utility exists if "the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do".[15] Note that the Supreme Court indicates that the broader meaning of utility is "what the specification promises" the invention will do.

An invention must serve to carry out some useful objective and "cannot be a mere laboratory curiosity whose only claim to utility is as a starting material for further research".[16]

The Patent Appeal Board has similarly noted that, in order to be useful in the sense required by the *Patent Act*, an invention must be controllable and reproducible such that the objectives of the invention are predictably achieved.[17]

Although an invention need only have one use in order to be patentable, where several uses are promised each must be properly established. For example, if a composition is promised to be useful as a drug in treating a specific disease, it must be established that it is useful in the therapy of that disease. If, however, it is promised to be useful as a drug for treating many diseases, its utility in treating all the diseases must be established in order for the specification to comply with subsection 27(3) of the *Patent Act* [see 17.04].

To clarify the foregoing, a promised use is one which the inventors assert their invention does have. Comments in the description that are clearly speculative in nature (relating, e.g., to what the inventors believe but do not know, to uses the invention might have, etc.) are not promises of utility.

Examples:

An inventor unexpectedly discovers that novel compound X is useful in treating disease Y (a disease of the kidneys), and files an application for this invention. The inventor has not yet discovered the mode of action of their drug, but rather has provided exemplary data to support the use.

1. In the description, the inventor suggests that "compound X may also be useful in treating other diseases of the kidneys". Nothing in the description supports that the compound has any utility other than in treating disease Y.

Analysis: The compound can be claimed on the basis of its unexpected utility. The statement in the description suggesting other possible utilities is clearly not an assertion by the inventor that the compound *will* treat other diseases of the kidneys, and does not cause any confusion on that point. No objection should be raised to the description on that point.

2. In the description, the inventor states that "compound X is also useful in treating other diseases of the kidneys such as A, B and C".

Analysis: The statement in the description is a clear assertion that compound X will treat the other diseases A, B and C. Unless the inventor is in a position to establish that it will in fact do so, the statement must be viewed as not correct and the description should be objected to under subsection 27(3) of the *Patent Act*. This is so whether the use of the compound to treat those diseases is claimed or not. If a claim is made to the use, the claim should also be objected to for being directed to subject-matter lacking in utility.

17.03.01 Establishing utility

The Supreme Court noted in *Apotex Inc. v. Wellcome Foundation Ltd.* that

> Utility is an essential part of the definition of an invention (*Patent Act*, s. 2). A policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove *invalidity*, without the patent owner's ever being put in a position to establish validity. Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner "by law" is required to refuse the patent (*Patent Act*, s. 40).[18]

Following 17.03, it is the invention's utility for achieving the objects indicated in the specification that the inventors must be in a position to establish.

Demonstrated utility pertains to embodiments of the invention that have been shown to actually work for the ends promised by the inventors. Utility can be demonstrated, for example, via working examples.

Soundly predicted utility pertains to embodiments of the invention which have not themselves been demonstrated to work for the ends promised by the inventors, but for which an appropriate basis exists upon which this utility can be predicted.

17.03.02 Sound prediction

In order for a prediction to be deemed to be "sound", it must meet the test set out in *Apotex*,[19] namely that there must be:

(i) a factual basis for the prediction;
(ii) an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and
(iii) proper disclosure.

It is important to keep in mind that a "sound prediction" does not imply certainty. It is clear from the very term "prediction" that this is so. At the same time, the Supreme

Court was clear in *Apotex* that a patent monopoly is not to be granted in return for mere speculation. Consequently, in assessing whether or not utility has been established via sound prediction the emphasis is appropriately placed on “sound”, and the question is whether a prediction is “sound” or “speculative”.

17.03.02*a* Factual basis

Evaluating what will be a sufficient factual basis for a sound prediction must be conducted on a case-by-case basis, and will depend on such factors as:

(i) the scope of the claims;
(ii) the state of the art;
(iii) the nature of the invention and its predictability; and
(iv) the extent to which the applicant has explored the area claimed, for example by conducting experiments which provide factual support for the utility asserted.

It is clear from *Apotex* that, while the factual basis may be provided by way of examples, there is no requirement that this be so.

As was noted in the case of *Pfizer v. Apotex*, however, “[u]tility and sound prediction are questions of fact and must obviously be supported [...]”.[20] Consequently, it seems clear that the term “factual” cannot be diluted to mean simple, unsubstantiated statements in the description promising that the invention will work.

As regards “prophetic examples”, while these are not per se objectionable they are of limited value in providing support. A prophetic example is necessarily a statement of what might be, rather than what is, and is therefore not “factual”.

17.03.02*b* Sound line of reasoning

In order to take a prediction from the realm of speculation and render it “sound”, the applicant must be able to provide to the person skilled in the art an explanation of how it is that, on the basis of whatever facts have been identified, of the state of the art, and of whatever the inventors have brought to light in their researches, the entire matter of the claimed invention can be expected to provide the promised utility. Since a sound line of reasoning is directed to a person skilled in the art, those elements of the sound line of reasoning that would be self-evident to the person skilled in the art in view of their common general knowledge do not need to be explicitly disclosed in the application.

Although no inventor is required to understand why their invention works, this does not dilute the requirements for a sound prediction. If an inventor cannot articulate a line of reasoning to soundly connect their factual support (e.g. their examples) to the remaining matter of their claims, they are not entitled to the full breadth of their claims.

It is not possible to provide exhaustive guidance on the types of reasoning which may be found to be "sound". This assessment depends on too many variables, and a factual basis which in one case may lead to a sound prediction may, in another case, be insufficient.

Knowledge of mechanisms of action and structure-activity relationships, however, are certainly compelling grounds upon which to base predictions. Similarly, in fields where *in vitro* tests are known to be predictive of *in vivo* activity, the *in vitro* tests could be sufficient for a sound prediction.

Where functional limitations appear in claims or are relied upon as the basis of a sound prediction, reference should be made to section 17.07.05.

17.03.02*c* Proper disclosure

The requirement for proper disclosure means that the person skilled in the art has to, through the specification interpreted in view of their common general knowledge, be provided with sufficient information to understand the basis of the sound prediction and to practice the entire scope of the claimed invention.[21]

Note that in making a proper disclosure, it is not necessary for the factual basis to be provided by way of examples. It is only necessary that the person skilled in the art would appreciate that the teachings of the description describe the necessary basis sufficiently, and that it is clear that the basis is factual. In certain cases, a reference to external, publicly-available data could suffice. Where the necessary factual basis is not publicly available as of the filing date it must be found within the description.

Determining whether or not the factual basis provided is sufficient must be assessed on a case-by-case basis in view of factors such as how developed the specific field is, how predictable inventions in that field are and the scope of the claims.

17.03.03 Relevant date

The date at which the applicant must be in a position to establish the utility of their invention is the filing date.[22] Consequently, the factual basis upon which either the demonstration or sound prediction is based must necessarily exist as of the filing date. Similarly, if a sound prediction is to be relied upon, the articulable and sound line of reasoning referred to in 17.03.02 must also exist as of the filing date.

Where an applicant is claiming priority, this claim is valid only insofar as the document or documents upon which it is based are sufficient to establish the utility of the invention.

Although an applicant is entitled to include in the application as filed matter not present in the priority document(s), where this matter is necessary to establish the utility of any embodiments of the invention those embodiments do not benefit from the priority date.

17.03.04 Office actions relating to utility

When an examiner has reason to believe that an applicant is not in a position to establish the utility of their invention, when the manner whereby they have attempted to establish utility is defective or when there is evidence of inutility an objection will be raised. The nature of the objection will depend on the specific defect, and should serve to communicate the severity of the perceived deficiency.

If the perceived defect in a claim is one of scope (i.e. the invention has been claimed more broadly than the description appears to support, such that the entire claimed matter does not appear to have the promised utility), an objection can be presented under section 84 of the *Patent Rules* on the grounds of a lack of full support.

Such an objection could be made, for example, because an element of the invention (an “essential” element) has not been defined in the claim.

Similarly, where it does not appear that a sound prediction exists upon which the utility of the entire scope of the claim can be predicated, such that the scope of the claim consequently does not appear to be “fully supported” by the description, a rule 84 objection is appropriate.

Objections under rule 84 suggest that the examiner views the defect in the claim as one of scope, and that it is remediable through amendment. If an applicant declines to amend, however, they are effectively asserting that the entire scope of the claim is their invention and in a subsequent report an objection to lack of utility (under section 2 of the *Patent Act*) and lack of sufficiency of disclosure (under subsection 27(3) of the *Patent Act*) could be raised.

Section 2 of the *Patent Act* requires that an invention be useful. Where an examiner has reason to believe that the invention as claimed lacks utility, and the matter is not of the nature described above in relation to rule 84, a section 2 objection is raised.

In *Monsanto Co. v. Commissioner of Patents*, it was noted that inutility should only be alleged on the basis of evidence of inutility or of a reasoned argument as to why the applicant's sound prediction of utility is defective.[23] An objection contending an applicant's sound prediction is flawed should be supported by setting out sufficient facts and reasoning to rebut the applicant's contention. The applicant must be given a sufficiently clear argument by the examiner that they are able to respond in an informed manner to those concerns raised by the examiner.

If the perceived defect is that the specification is, in view of the criteria set out in *Apotex*, insufficient to support a sound prediction, this should be clearly communicated. Where the defect is of the nature that no factual basis appears to exist or that no line of reasoning appears to exist (whether by explicit disclosure or in view of the common general knowledge of the person skilled in the art), the "reasoned argument" can be simply identifying these apparent omissions. In such cases, the objection to the claims under section 2 of the *Patent Act* should be accompanied by an objection to the description under subsection 27(3) of the *Patent Act*.

Conversely, even where an applicant has demonstrated and/or soundly predicted the utility of their invention, it may be the case that some basis exists (a factual basis such as data in the prior art, contravention of a law of science etc.) to contend inutility in regard to some embodiment of the invention. When such a basis can be identified, even as regards only one embodiment of a broad claim, the whole claim is objected to on the ground of a lack of utility.

It should be noted that evidence of inutility can be provided at any time. There is no requirement that such evidence existed as of the application's claim date.

Examples:

1. The description as filed includes a statement indicating that proteins having 80% sequence identity to SEQ ID NO: 1 are useful as anti-cancer compounds in humans. No other utilities are disclosed. The sequence in SEQ ID NO: 1 is that of a novel protein bearing only a slight structural similarity (< 20%) to a known protein, and the protein's functional activity is not disclosed. No test data of any kind is included in the description.

Claims:

1. A protein comprising the amino acid sequence depicted in SEQ ID NO: 1.

2. A protein which has at least 80% sequence identity to SEQ ID NO: 1.

3. A pharmaceutical composition comprising a protein as defined in claim 1 or 2 for use as an anti-cancer drug.

Analysis: The description does not contain any factual basis to support a sound prediction that the protein having the sequence provided in SEQ ID NO: 1 is useful as an anti-cancer compound. Given that the protein has only a slight structural similarity to a known protein, extrinsic data does not seem to exist. Neither has any data supporting the promised utility been provided in the description. Consequently, the description appears to be insufficient and is objected to under subsection 27(3) of the *Patent Act*. Similarly, as it is not clear that the inventor is in a position to establish the utility of their invention for the promised purpose, the claims are objected to under section 2 of the *Patent Act*. It is up to the applicant to attempt to explain how they have met the utility requirement identified in *Apotex*.

2. The description as filed discloses an outer membrane protein [SEQ ID NO: 1] from a bacterium which is involved in a human disease X. The description provides pre-clinical data showing that the protein generates a protective immune response when used in a monkey model of disease X. It is understood from the description that the data from the monkey model is predictive of success in humans in view of the model's demonstrated success in predicting the activity of similar known antigens.

Claims:

> 1. A protein comprising the sequence defined by SEQ ID NO: 1.
>
> 2. A vaccine for use in protecting a human subject from disease X, comprising a protein having the sequence defined by SEQ ID NO: 1 and an adjuvant therefor.

Analysis: The description provides data demonstrating the activity of the protein for the promised purpose in monkeys. Extrinsic data, identified in the description, exists to support the utility of the monkey model for predicting human activity of similar antigens. A person skilled in the art would appreciate that this factual basis, properly disclosed in the description, is sufficient to allow the utility of the protein of claim 1 to be soundly predicted.

17.04 Sufficiency of the description

Closely related to the question of utility is that of sufficiency. Subsection 27(3) of the *Patent Act* requires (*inter alia*) that the description "correctly and fully describe the invention and its operation or use as contemplated by the inventor". Thorson P. summarized the requirements for sufficient specification in *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*, and later described this "onus of disclosure" as "a heavy and exacting one".[24]

> The description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and must be as simple and distinct as the difficulty of description permits. It must not contain erroneous or misleading statements calculated to deceive or mislead the persons to whom the specification is addressed and render it difficult for them without trial and experiment to comprehend in what

> manner the invention is to be performed. It must not, for example, direct the use of alternative methods of putting it into effect if only one is practicable, even if persons skilled in the art would be likely to choose the practicable method. The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed.[25]

As was noted in section 17.03, the description must contain sufficient information to support a sound prediction of the utility of the invention. Further, it must set out the invention such that a person skilled in the art can practice it having reference only to the description itself and to common general knowledge.

In *Consolboard*, Dickson J. noted that "the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired".[26] The description must be able to answer the questions "What is your invention?: How does it work?"[27] such that "when the period of the monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application".[28]

A description sufficient to allow the public (in the form of a person skilled in the art) to practice the invention is said to be enabling. Since the person skilled in the art is the addressee of the description, it is not necessary for common knowledge to be comprehensively disclosed. A known assay technique does not need, for example, to be taught in full. Merely referring to this technique is sufficient for the person skilled in the art to know how to practice it.

When an examiner has reason to believe that a description is deficient for not having correctly and fully described the claimed invention, an objection is raised under subsection 27(3). This might be the case, for example, when a broad claim is supported only by its own verbatim language.

It is important to bear in mind that the specification must be sufficient to allow the full scope of the claimed invention to be practised without the need for the person skilled in the art to exercise their inventive ingenuity. If the person skilled in the art is called on to solve problems in such a manner that an inventive step would be present, the description is insufficient (and the attendant claims are unsupported).

17.04.01 Sequence listings

The following sections apply to applications filed on or after June 2, 2007. For applications filed prior to that date, the applicant may substitute the requirements of sections 111 to 131 of the *Patent Rules* as they read immediately prior to the coming into force of the current rules for the requirements of section 111 of the *Patent Rules.* Similarly, the requirements of section 62 as it read immediately prior to the coming into force of the current rules may be substituted for the requirements of section 94 of the *Patent Rules.* Guidance on the application of previous versions of the *Patent Rules* can be had by reference to an earlier version of this manual.

17.04.01*a* Requirement for a sequence listing

In accordance with subsection 111(1) of the *Patent Rules*, if an application discloses "a nucleotide or amino acid sequence other than a sequence identified as forming a part of the prior art, the description shall contain, in respect of that sequence, a sequence listing in electronic form, and both the sequence listing and the electronic form shall comply with the PCT sequence listing standard".

When this is the case, the provision of said sequence listing is a requirement for completion of the application (whether or not the application is a PCT national phase application). Section 94 of the *Patent Rules* requires that the sequence listing be provided to the Office within the later of twelve-months from filing or three months of a notice requisitioning its provision. Where a sequence listing is requisitioned by the Office, the fee set out in item 2 of Schedule II is payable. To avoid the requirement to pay this fee, the applicant must provide any required sequence listing within "the applicable time". For an application other than a PCT national phase application, the applicable time is 15 months from the earliest priority date or, where no priority is claimed, 15 months from the filing date. For a PCT national phase application, the applicable time is 3 months from payment of the requisite fees for national entry and provision of a copy of the application and/or a translation of the application if applicable (i.e. the requirements of subsections 58(1) and 58(2) of the *Patent Rules*).

When a sequence listing submitted in accordance with subsection 111(1) of the *Patent Rules* is of record in the Office, it is not permissible for a paper copy of the sequence listing to be of record. Applicants will be requisitioned to withdraw any paper copy of a sequence listing for which a PCT sequence listing standard-compliant (see 17.04.01*b*, below) electronic sequence listing has been made of record.

17.04.01*b* The PCT sequence listing standard

The term "PCT sequence listing standard" refers to the *Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in International Patent Applications Under the PCT.* This standard is provided in annex C of the *Administrative Instructions under the PCT* and is available at http://www.wipo.int/pct/en/texts/pdf/ai_5.pdf

17.04.01*c* Addition of a sequence listing to an application

In accordance with subsection 111(2) of the *Patent Rules*, if a sequence listing is added to an application originally filed without a sequence listing, "the applicant shall file a statement to the effect that the listing does not go beyond the disclosure in the application as filed".

17.04.01*d* Amendment of a sequence listing

In accordance with subsection 111(3) of the *Patent Rules*, if an application as filed contains a sequence listing either in paper form or in an electronic form that does not comply with the PCT sequence listing standard and the applicant replaces the non-compliant sequence listing "by a sequence listing in electronic form that does comply with that standard, the applicant shall file a statement to the effect that the replacement listing does not go beyond the disclosure in the application as filed".

17.04.01*e* Correction of a sequence listing

If a sequence listing is found to contain errors, any correction of the listing must comply with the requirements of subsection 38.2(2) of the *Patent Act*. That is, no new matter may be added to the specification or drawings as originally filed and any correction made to a sequence listing must be reasonably inferrable from the specification or drawings as filed. Where the correct sequence could only be determined by, for example, re-sequencing a sample, the correction is not reasonably to be inferred.

17.04.01*f* Identification of a sequence listing

In accordance with subsection 86(3) of the *Patent Rules*, the claims may refer to sequences represented by sequence listings by the sequence identifier and preceded by "SEQ ID NO:". The sequence identifier can simply be an arabic numeral, such that the first sequence identified in the description could be identified as SEQ ID NO: 1, the second as SEQ ID NO: 2, etc.

17.04.01*g* Usage of variable symbols in a sequence listing

The use of the symbols "n" (or "N") and "Xaa" to define "unknown or modified" bases and amino acids, respectively, is discussed in paragraphs 10 and 18 of the PCT sequence listing standard. When these symbols are used in a sequence listing, they can represent only a single residue (nucleotide or amino acid, respectively) at a specific position in the sequence.

The Office considers that the residues represented by the symbols "n" (or "N") and

"Xaa" may be defined in the "Features" section as being either present or absent, and that these symbols may also be used to define that a standard nucleotide or amino acid residue is either present or absent. Similarly, these symbols can be used, through the definitions given in the "Features" section, to represent alternate residues at a given position.

Note that since such symbols represent only a single residue, a sequence of variable length must be presented by using a sufficient number of discrete symbols to represent the maximum length of the sequence. Symbols used in such a presentation may then be qualified in the "Features" section to be either present or absent.

The foregoing discussion relates only to the manner in which the foregoing symbols may be used as a matter of nomenclature. During examination, an examiner must consider whether or not the use of such symbols is objectionable, for example on the grounds of lack of clarity or support.

17.04.02 Deposits of biological material

Section 38.1(1) of the *Patent Act* provides that:

> *Where a specification refers to a deposit of biological material and the deposit is in accordance with the regulations, the deposit shall be considered part of the specification and, to the extent that subsection 27(3) cannot otherwise reasonably be complied with, the deposit shall be taken into consideration in determining whether the specification complies with that subsection.*

Section 38.1(2) of the *Patent Act provides that:*

> *For greater certainty, a reference to a deposit of biological material in a specification does not create a presumption that the deposit is required for the purpose of complying with subsection 27(3).*

Therefore, it can be seen from the language of the *Act* that a deposit may be made whether or not it is necessary to enable the invention. Where the invention cannot be enabled [see 17.04] in the absence of access to a biological material, however, the deposit is a necessary element to make the description sufficient unless the required material is publicly known and reliably available to the person skilled in the art. A biological material is considered to be reliably available if it can be obtained commercially or can be reproducibly prepared or isolated from available materials using established procedures and without undue experimentation.

The presence of a biological deposit does not change the requirements of subsection 27(3) of the *Patent Act* except, as provided by subsection 38.1(1) of the *Patent Act*, to the extent subsection 27(3) cannot otherwise reasonably be complied with. The fact that a biological deposit has been made does not of itself mean that an invention has been adequately described.[29] A claim to a desired product does not merit protection simply because reference is made to where the product can be found.

Whenever possible, it is preferable that both methods of disclosure should be used.[30]

For example, consider an application that claims an uncharacterized gene by reference to a deposit of a micro-organism containing the gene. The deposit is not a substitute for a full and complete description of the gene itself and, in view of subsection 38.1(1) of the *Patent Act* (vide supra), would not of itself meet the requirements of subsection 27(3) of the *Patent Act*.

Sections 103 to 110 of the *Patent Rules* regulate deposits of biological material. The practical aspects of biological deposits covered by these rules are dealt with in Appendix 1 of this chapter.

17.04.03 Inclusion of examples

Given the complexity of some biotechnology inventions, it is not always feasible for an applicant to provide a complete description of their invention by words alone. This is acknowledged, e.g., by the presence of section 38.1 of the *Patent Act*.

Although there is no absolute requirement under subsection 27(3) of the *Patent Act* for an application to include examples, the practical effect of the complex nature of some biotechnology inventions is that it may not be possible for an applicant to fulfill the "what is your invention" [see 17.04] aspect of proper disclosure without exemplary support for their invention. Whether or not exemplary support is necessary must be assessed on a case-by-case basis, in view of the completeness of the remainder of the written description.[31]

Paragraph 80(1)(f) of the *Patent Rules* notes that the description of an invention must

> *set forth at least one mode contemplated by the inventor for carrying out the invention in terms of examples, where appropriate, and with reference to the drawings, if any...*

The use of the wording "where appropriate" in this rule reflects that an exemplary basis may or may not be necessary depending on the case at hand. The language "where appropriate" does not merely mean "if the applicant deems it appropriate", and does not provide any exception to the requirements of subsection 27(3) of the *Patent Act*.

17.05 Novelty

As with any invention, a biotechnology invention must be new (novel). Generally, whether an invention is novel or not is answered by asking whether or not it is known in the art (i.e. anticipated).

For a prior disclosure to be anticipatory, it must describe the invention being claimed and provide an enabling disclosure of that invention. An invention is considered to have been previously described where the subject-matter previously disclosed would, if performed, infringe the later claim. A prior disclosure is considered to be enabling for the purposes of anticipation where the person skilled in the art, if necessary through trial and error experimentation that is neither inventive nor an undue burden, can operate it successfully.[32]

The various tests articulated in the cases *Reeves Bros. v. Toronto Quilting*[33] and *Beloit Canada Ltd. v. Valmet* Oy[34] deal with the aspect of prior disclosure, and their guidance in terms of a requirement for an "exact description" of the same invention must be understood in this context.[35] Note that in *Diversified Products v. Tye-Sil*, the Court discussed the tests provided in both *Reeves Bros.* and *Beloit* with no suggestion that the various tests found in the two cases are mutually inconsistent.[36] It can therefore be concluded that a claim lacks novelty if any one embodiment falling within its scope is described according to the standard expressed in *Beloit*.

Thus, the anticipatory disclosure must provide all the information necessary, for the purposes of practical utility, to lead the person skilled in the art directly and without difficulty to at least one embodiment of the invention in suit. Further, the prior disclosure must be enabling of the embodiment which is allegedly anticipated.[37]

By way of non-limiting examples, it is noted that a claim to a composition of matter is anticipated if a composition of matter falling within that claim has already been made or, where one such composition of matter has not been made, but nonetheless has been described and enabled and its actual utility soundly predicted.

17.05.01 Biological materials

Recall from 17.04.02 that a description may be considered not to be sufficient unless it provides access, via a deposit made as of the filing date, to biological material associated with the invention. This requirement extends to an allegedly anticipatory disclosure.

Consequently, if the disclosure found in the prior art requires, in order for the invention described therein to be practised, access to a biological material, the biological material must necessarily have been reliably available to the person skilled in the art in order for the document to be anticipatory. To be reliably available it must be either commercially available, be reproducibly preparable or isolable from available materials using established procedures and without undue experimentation, or be accessible via a deposit of biological material.

Examples:

1. Prior art journal article D1 published by the applicant discloses the discovery of a specific hybridoma (hybridoma X) that produces a monoclonal antibody (antibody Y) which is specific for antigen Z. There is no indication in the journal article that a deposit of hybridoma X has been made.

Claims:

1. Hybridoma X deposited as ATCC 1234 which produces antibody Y.

2. A hybridoma which produces a monoclonal antibody capable of binding antigen Z.

Analysis: claim 2 broadly defines "a hybridoma", and the prior art does in fact disclose such a hybridoma. Claim 2 lacks novelty. Claim 1, in contrast, defines specifically hybridoma X. The person skilled in the art could not reliably obtain hybridoma X simply by following the methodology disclosed in the article (i.e. they could get a hybridoma which would produce a monoclonal antibody for antigen Z, but not necessarily hybridoma X). To reliably produce X they would need access to a deposit of X. Without this deposit, the prior art article is not anticipatory of claim 1. (N.B. There remains, of course, the question of whether or not claim 1 has an inventive step.)

2. Prior art journal article D1 describes a plasmid constructed from various known genetic elements using known methods. The genetic elements were also freely available to the public. The plasmid is termed "plasmid X" but has not been deposited.

Claim:

1. Plasmid Y [which has the very same features and arrangement as plasmid X] deposited as ATCC 1235.

Analysis: the claim is anticipated since the claimed plasmid is indistinguishable from the known plasmid X and since a person of skill in the art would be able to construct plasmid Y using known, freely available, genetic elements and methods.

17.05.02 Inherent or implicit disclosure

An enabling disclosure is considered to disclose all the inherent properties of the invention. Old and known subject matter is not rendered novel by including a limitation which is inherently or implicitly found in the prior art.[38]

For example, consider that a prior art document discloses a chemical compound X and how to make it, and establishes that compound X is useful in treating disease Y. Where subsequent research uncovers the mechanism of action of the compound, a claim to the use of compound X to treat disease Y via the newly discovered mechanism is not novel. Compound X implicitly treated disease Y via the mechanism, and the discovery has not led to a new use for the known compound.[39]

Where anticipation is predicated on the presence of an inherent or implicit feature, it is necessary to clearly explain the grounds on which the presence of that feature in the matter of the prior disclosure is concluded. Where such a conclusion is supported by secondary references, the date of publication of these references is not important.

Examples:

1. A prior art document discloses a prepared cosmid whose DNA sequence record contains a sub-sequence identical to SEQ ID NO: 1. The record does not disclose any information on the coding capabilities of the cosmid.

Claim:

1. A nucleic acid molecule comprising SEQ ID NO: 1 which encodes an [novel] enzyme having protease activity.

Analysis: the claim is anticipated. The use of the term "comprising" indicates the claim is open-ended and encompasses any nucleic acid molecule, including a cosmid, which minimally contains the structure depicted in SEQ ID NO: 1. Since coding capability inevitably follows from the structure of the sequence itself, this functional feature does not impart novelty over the prior art. Effectively, the claim is asserting that every nucleic acid having the defined structure will encode an enzyme having protease activity. The prior disclosure of the cosmid is anticipatory. A claim to a nucleic acid molecule consisting solely of the sequence defined in SEQ ID NO: 1 would, however, not be anticipated.

2. A prior art journal publication discloses the amino acid sequence (SEQ ID NO: 1) of a naturally occurring protein.

Claim:

1. A protein comprising the primary amino acid sequence identified in SEQ ID

NO: 1 and having a three-dimensional structure defined by the newly discovered atomic coordinates depicted in figure 1.

Analysis: the claim is anticipated since the claimed protein appears to be identical to the old and known protein disclosed in the prior art and since the limitation found in the claim which identifies the three-dimensional structure of the protein is something which has been implicitly disclosed. Although the atomic coordinates of the protein may represent something that is newly disclosed, this information is not regarded as something which distinguishes the claimed protein *per se* over the prior art.

17.05.03 Products-by-process

A product may be defined in terms of the process by which it is prepared. It must always be remembered that product-by-process claims are, simply, directed to products. In relation to novelty, therefore, it must be evident that all the products falling within the scope of a product-by-process claim are new.

A known product cannot be patented merely because it has been prepared by a new process.[40] This is so regardless of the nature of the process. Where a process inevitably results in a product having distinct technical features, however, novelty exists.

A claim to, e.g., "protein X prepared by recombinant means" lacks novelty where protein X is known and is indistinguishable from the protein defined in the claim. If the recombinant process to prepare a protein similar to protein X, however, consistently results in the presence of novel post-translational structural features, a claim to "protein X' prepared by recombinant means" would be novel.

17.06 Ingenuity

As with any invention, a biotechnology invention must comply with the requirements of section 28.3 of the *Patent Act*. The invention as claimed must consequently not be obvious or, equivalently, must be the result of inventive ingenuity.[41] It has been noted by the courts that the addition to the *Patent Act* of section 28.3 merely codified what was already accepted, and has not changed the inherent requirement that an invention be the result of ingenuity.[42] Thus, the courts have noted that "obviousness is an attack on a patent based on its lack of inventiveness"[43] and "[t]he courts have chosen to define 'lack of inventiveness' rather than 'inventiveness' and have called it 'obviousness'".[44]

To meet the requirement of section 28.3 of the *Patent Act* there must, in view of the state of the art and the common general knowledge as of the claim date, be present that "characteristic or quality" (i.e. a "scintilla of inventiveness") which serves to elevate the matter of the claims from mere workshop improvement to real invention.[45]

When comparing the matter of the claims to teachings found in the prior art, it is usual to approach the question by asking whether or not the prior art renders the claimed invention obvious. It has been noted that no single test for obviousness exists that can be appropriately applied to all inventions.[46] Rather, several factors should be considered, including the level of common general knowledge of the person skilled in the art, the climate in the relevant field at the time the alleged invention was made, and whether there was motivation in existence at that time to solve a recognized problem.[47] It can also be relevant to consider whether certain matter would have been "obvious to try" at the date of invention, but this factor must be approached cautiously, and considered in view of whether the person skilled in the art would have both the motivation to perform certain routine experiments and a reasonable expectation of success in making these inquiries.[48]

An invention can be found to be obvious if the question set out in *Beloit*, when asked in the proper context, is answered in the affirmative. This question may be paraphrased as: would a person skilled in the art, in view of the state of the art and their common general knowledge as of the claim date, have come directly and without difficulty to the solution taught by the patent.[49] The aspect of "directly and without difficulty", in view of the more recent guidance set out in the previous paragraph, must not be interpreted too narrowly.

17.06.01 Nucleic acids encoding amino acid sequences

If given the amino acid sequence of a polypeptide, the entire class of nucleic acids encoding it can be generated through simple deduction; *i.e.*, by using the genetic code to back-translate from the amino acid sequence. Therefore, a generic claim to a nucleic acid encoding a known amino acid sequence is considered obvious.

The opposite is also considered obvious. An amino acid sequence encoded by a known nucleic acid can be directly derived through the translation of the known coding nucleic acid provided the correct reading frame has been identified or is obvious.

Given that the class of nucleic acids encoding any particular polypeptide is astronomically large, the identification of a species of the class which has unexpected or advantageous properties can be inventive. The test for a proper selection (see 17.07) should be applied.

Example:

1. A prior art journal article D1 discloses the amino acid sequence (SEQ ID NO: 1) of a 30 amino acid long mammalian peptide whose sequence was derived through Edman degradation. There are no indications that recombinant

techniques were used nor is there an explicit disclosure of a nucleic acid molecule which encodes the peptide. A review article D2 discusses methods and codon usage tables that may be used in order to achieve enhanced expression of heterologous genes in plant tissues.

Claims:

1. A nucleic acid encoding the peptide identified by SEQ ID NO: 1.

2. A nucleic acid which has been optimized for expression in plant tissue and which encodes the peptide identified by SEQ ID NO: 1.

3. A nucleic acid comprising the sequence identified by SEQ ID NO: 2 which has been optimized for expression in plant tissue and which encodes the peptide identified by SEQ ID NO: 1.

Analysis: consider that the application properly discloses that the sequence identified by SEQ ID NO: 2 is particularly advantageous for use in encoding the peptide identified by SEQ ID NO: 1. Consider that it would not be obvious to the person skilled in the art that this would be so.

Claim 1 is obvious in view of D1 alone for two reasons. Firstly, the claim does not refer to any nucleic acid in particular and merely reflects the general idea of having a nucleic acid molecule which is capable of encoding the peptide; an idea that a person of skill in the art would readily appreciate in view of D1. Secondly, the prior art provides the amino acid sequence of the peptide making it a simple matter of deduction for the person of skill in the art to generate a nucleic acid sequence capable of encoding the peptide.

Claim 2 is obvious in view of D1 in combination with D2. The claim does not refer to any nucleic acid in particular and again merely reflects, albeit in a somewhat more restricted sense, the general idea of having a nucleic acid molecule which has been optimized for expression in plant tissue; an idea that a person of skill in the art would readily be able to put into practical effect by deducing an appropriate encoding sequence from D1 in view of the more specific guidance offered by D2.

Claim 3 is not obvious since neither reference discloses nor suggests the particular sequence referred to in the claim and since, based on the description, the sequence appears to have unexpected properties. The claim represents the selection of nucleic acids having a particular sequence from amongst the genus of all possible nucleic acids encoding the peptide and from amongst the subgenus of all possible nucleic acids employing plant optimized codons.

17.06.02 Process claims

A claim to a generic "process for cloning or obtaining a gene encoding a known polypeptide" (of unknown sequence) which relies on generally known methods is considered obvious unless the gene is novel and patentable and the claim contains an explicit indication of its structure.

17.07 Claims

In claiming biotechnology inventions, many different approaches can be taken. Here again, there are no special rules with respect to biotechnology. A claim to a biotechnology invention must consequently be of definite and unambiguous scope,[50] must serve to distinguish the claimed invention from the prior art, must explicitly define all those features necessary to enable the person skilled in the art to realize the promised utility, and must be fully supported by the description. The claims, individually and collectively, must be clear and concise and leave the reader in no doubt as to the nature of the invention. These, collectively, are the usual requirements demanded by subsection 27(4) of the *Patent Act* and section 84 of the *Patent Rules*.

17.07.01 Selections

Many inventions are predicated on the selection from a genus of one or several species. The criteria for a proper selection were clearly stated by Maughan J. in the UK case *I.G. Farbenindustrie A.G.'s Patents*,[51] and have been repeatedly cited with approbation in Canadian jurisprudence.[52]

To be a proper selection, the matter of the selection must be:

(i) based upon a substantial advantage; and
(ii) the whole of the selection must possess the advantage; and
(iii) the advantage must be in respect of a special quality or character common to the whole of the selection.

An important consideration that must be borne in mind is that while embodiments being selected have been disclosed in some generic manner in the prior art, no embodiment falling within the scope of the claim can actually have been prepared. Per Maughan J., "[i]t must be remembered, of course, that the selected compounds have not been made before, or the patent would fail for want of novelty".[53]

A selection, therefore, is based entirely on the recognition by a later inventor of an advantage present in some subset of an invention more broadly disclosed in the prior art. To be novel, the selection cannot encompass any embodiments that have been previously practiced. To be inventive, the entire matter of the selection must possess the advantage. To be a single inventive selection, the advantage must be in respect of a special quality or character common to the whole of the selection.

The utility of a selection depends on the presence of the "substantial advantage", and it is this utility that the applicant must be in a position to establish by demonstration or sound prediction. Note that the "substantial advantage" may be a disadvantage that is avoided by the selection.[54]

Example:

1. Prior art patent D1 discloses the utility of a known genus of polypeptides (genus A) for a new medicinal use (treating condition Y).

Claim:

1. The use of polypeptide A1 for use in treating condition Y.

Analysis: consider that polypeptide A1 is a member of genus A which was not exemplified in D1. Consequently, its therapeutic activity had not previously been conclusively demonstrated. Consider that the application in question does not provide any exemplary data that polypeptide A1 has properties superior to those of other members of the genus in general. The application provides prophetic examples suggesting polypeptide A1 may be a suitable (even advantageous) alternative to the specific polypeptides mentioned in D1 as examples of genus A. As the prophetic examples suggest the utility is being predicted, it appears there is no factual basis upon which the selection can be fairly based. The matter of the claim, consequently, does not appear to be the result of an inventive step. Rather, it is an arbitrary selection of one of a group of equivalents known in general for the treatment of condition Y.

17.07.02 Provisos

Applicants will sometimes exclude certain embodiments from their claims, usually to avoid inoperative embodiments, known prior art disclosures, or their own copending applications.

While the use of provisos is acceptable, the effect of the proviso on the application as a whole must be carefully considered. Note that in the present discussion, the term "proviso" has been used as a generic term to refer to the exclusion of matter from a claim by negative limitation. Whether the proviso is indicated using language such as "provided that A is not B", "wherein X is not Y", "any <generic element> except Q", or some other form is not material.

The effect of a proviso on a claim will depend on the specific circumstances of each application, and should be carefully considered. A proviso not disclosed in the application as filed, for example, has the potential of introducing subject-matter not reasonably to be inferred from the specification as originally filed, and consequently as being contrary to subsection 38.2(2) of the *Patent Act*. No presumption exists that the introduction of a proviso not disclosed at filing is automatically the addition of new subject-matter.

17.07.02*a* Provisos and utility

Where a proviso has been presented to avoid inoperative subject-matter, the basis upon which the utility of the remaining matter of the claim has been established must be reconsidered. Since utility will often be based on a sound prediction, a proviso to exclude a known inoperative embodiment requires that the line of reasoning upon which the utility of the remaining matter of the claim is based be reassessed.

17.07.02*b* Provisos and unity

In certain cases, the presence of a proviso will call into question whether the remaining matter of the claims defines a single invention. For example, if a claim defines the use of NSAIDs in combination with another drug to treat some disease, but it excludes ASA, a question arises as to the common general inventive feature upon which the unity of invention is based. It is no longer the use of NSAIDs, since ASA is excluded. This feature is no longer “common” to the invention. It is not the use of a combination therapy to treat a disease, since unity cannot be predicated on a desired result to be achieved, but must rather be resident in the means of achieving the result.

17.07.02*c* Provisos and non-essential elements

The situations referred to in the previous sections generally relate to the use of provisos to exclude embodiments that are members of broadly disclosed essential features (e.g. ASA from the essential element “NSAIDs”). Where a proviso is used to exclude in an arbitrary fashion some non-essential feature, this approach will generally not be sufficient to establish novelty or inventive step over the prior art.

Examples:

1. A prior art journal publication D1 discloses murine and bovine growth factor polypeptides. The polypeptides are 85% and 87% identical over their entire length to a human growth factor (SEQ ID NO: 1) disclosed in the application in question.

Claim:

1. A growth polypeptide comprising at least 80% identity to SEQ ID NO: 1,

provided that said polypeptide is neither the polypeptide depicted below in (a) nor the polypeptide depicted below in (b):

(a) [murine growth factor amino acid sequence];
(b) [bovine growth factor amino acid sequence].

Analysis: consider that the proviso was introduced after D1 was cited against the claim. The addition of the proviso does not serve to render the claim patentable over the prior art. D1 calls into question whether the matter of the post-proviso claim is based on a common inventive step in regards to the state of the art. In view of D1, it would be obvious that many polypeptides having sequences within the claimed range would provide the same utility.

2. Prior art application D1 discloses compound X as a useful drug in the therapy of disease Y.

Claim:

1. A compound having <structural element A> for use in treating disease Y, provided said compound is not compound X.

Analysis: consider that at the time D1 was filed, the applicant did not know what structure led to compound X's activity. They have now discovered through further research what structure leads to the drug's activity, and wish to claim other drugs related to X via this structure which are useful for the same purpose. The proviso is acceptable in this instance, because the invention of claim 1 is not rendered obvious by D1 and the disclaimer is not arbitrary in nature.

17.07.03 Reach-through claims

As noted in section 17.04, “nothing that has not been described may be validly claimed”. A claim to subject matter which extends beyond the invention adequately described is sometimes termed a “reach-through claim”. Reach-through claims typically define products that will be useful for some purpose, but which have not yet been identified.

For example, if an applicant discloses a method for screening drugs for use in treating a certain disease, a claim to useful drugs identified by the method would be a reach-through claim. The claim “reaches through” the method to define the useful products it might identify. Since such products have not yet been identified, they cannot be properly described per se. Similarly, an invention directed to a method of identifying receptor ligand antagonists may not be legitimately extended to generally claim all antagonists which might eventually be discovered through the use of the inventive method.

In the case of a nucleic acid molecule encoding a protein, the provision of a partial amino acid sequence of the protein is not taken as an adequate description of a nucleic acid molecule which is capable of encoding the entire protein.[55]

17.07.04 Functional limitations

In certain cases, applicants may wish to define an invention using functional language. The use of functional language is not per se objectionable. Such language is generally used to provide breadth, however, and must be carefully considered from the perspective of proper support.

Functional limitations must always be considered from the perspective of the person skilled in the art, and the question to be asked is: "can the person skilled in the art practice the full breadth of the claim without recourse to inventive ingenuity?". If the means to effect the defined function are common general knowledge, the functional limitation is unlikely to be objectionable. Where few or only one means is known to effect the function, however, the functional term exceeds the appropriate scope of the invention by seeking to monopolize speculative embodiments the inventors could not be considered to have adequately described.

To paraphrase *Free World Trust v. Électro Santé Inc.*, "it is not legitimate to invent a particular composition that grows hair on bald men and thereafter claim all compositions that grow hair on bald men".[56] Thus, a claim to "a composition comprising a hair-growth activating compound in a pharmaceutically acceptable carrier", where only compound X is known to provide the function, would be too broad. The limitation "hair-growth activating" is a functional limitation to the scope of the compounds found in the composition, but does not serve to make the scope of the claim clear to the person skilled in the art. Identifying all the compounds that would have this activity would require extensive inventive experimentation.

In contrast, where it has been discovered that the combination of a particular drug with any NSAID leads to unexpected advantages, the functional limitation "non-steroidal anti-inflammatory" on the scope of the second component of the composition would not be problematic. The scope of the term "NSAID" would be immediately apparent to the person skilled in the art.

Example:

1. An application describes a novel polypeptide [SEQ ID NO. 1] which is shown to arrest the growth of breast cancer cells *in vitro*.

Claim:

1. A pharmaceutical composition for use in the treatment of breast cancer

> comprising a polypeptide capable of arresting the growth of breast cancer cells and a pharmaceutically acceptable carrier.

Analysis: the claim is overly-broad since the claim fails to include structural features of the "novel polypeptide" and since the description describes with particularity only one polypeptide with the desired property, being that having the structure depicted in SEQ ID NO. 1. Thus, in a first report an objection under section 84 of the *Patent Rules* is warranted, as the claim defines more than the description supports. Note that no related objection is made in this report under subsection 27(3) of the *Patent Act* as long as the description correctly and fully describes the invention in regards to the "novel polypeptide". Note that in a further report, this objection might need to be raised under section 2 of the *Patent Act* with an accompanying objection under subsection 27(3), for example if the applicant argues that the presence of literal support for claim 1 is sufficient to enable the full scope of the claim [see sections 17.03.04 and 17.04].

17.07.05 Scope of claims

In order to fulfill their public notice function, a claim must define the invention in such a manner that the person skilled in the art will understand where they may and may not go without infringing.

As Lord Loreburn noted in *Natural Kinematograph Co. v. Bioschemes Ltd.*, "[t]he patent system is designed to advance research and development and to encourage broader economic activity. Achievement of these objectives is undermined however if competitors fear to tread in the vicinity of the patent because its scope lacks a reasonable measure of precision and certainty. A patent of uncertain scope becomes a public nuisance".[57]

An objection to a claim for ambiguity or lack of clarity as to its limits (indefiniteness) is made under subsection 27(4) of the *Patent Act*. A claim is not indefinite simply because it is broad, but rather where the precise limits of the claim are uncertain. A claim that relies, for example, on the use of "a polyol" is not indefinite since the person skilled in the art can immediately appreciate the scope of that term. A claim relying on "a polyol capable of <performing some function>", however, is indefinite if the person skilled in the art would not know, or be able to reasonably predict or determine, what polyols fall within the scope of the claim.

17.07.05*a* Recourse to the description

During examination, the language of the claims is interpreted by giving each term its plain and usual meaning in the art to which the invention pertains unless it is clear from the description that a term in the claims is to be given a different meaning.

The courts have acknowledged that an applicant can act as their own lexicographer, by specifying in their description that certain terms will have particular meanings for the purposes of the application. Whenever an applicant is desiring to act as their own lexicographer, however, it is incumbent on them to make this clear from the language of the description. Further, in so acting it is not proper to give a term having a well-known meaning a definition which is contrary to this meaning. In such cases, uncertainty exists as to whether the term, when found in a claim, is intended to have its usual or distorted meaning.

For example, teaching that the term "up" means "down" for the purposes of the invention is only liable to cause confusion and serves no purpose. Such a definition, when made in the description, would be objected to under subsection 27(3) of the *Patent Act*. Further, the claim containing the term "up" is objected to under subsection 27(4) of the *Patent Act* for the lack of clarity as to whether the term is intended to actually mean "up", or rather to mean "down" following the teachings of the description. Similarly, teaching that the symbol "P" indicates nitrogen atoms is misleading; the symbol is recognized in chemistry as designating phosphorus, and could readily be replaced by the appropriate symbol "N" to designate nitrogen. In contrast, teaching that the term "protein", for the purposes of the invention, has some specific but sensible meaning could be acceptable, especially where this avoids having to repeatedly include a lengthy definition in the claims.

Whenever inclusion of the definition found in the description into the claims would not be detrimental to the clarity and conciseness of the claim, however, this should be done.

It is worth noting that the courts, in construing the claims of a patent, are dealing with a document whose language is fixed. Any deficiencies in the language of the claim can only be remedied by construing the claim in "an informed and purposive way". During examination, in contrast, the language of the claims may be amended so as to remove ambiguity and maximize their usefulness in serving their public notice function of defining the extent of the monopoly sought.[58]

Where a defect of clarity has been noted by an examiner in the language of a claim, it will generally be maintained in the face of a response arguing that the courts could, with the assistance of expert testimony, arrive at some construction thereof. The purpose of the claims is to serve a public notice function, and "nothing can excuse the use of ambiguous language when simple language can easily be employed".[59]

17.07.05*b* Defining biomolecules by structure

According to section 11.08, a product may be defined in three ways: by structure, in terms of the process by which it is made, and in terms of physical or chemical properties. The most explicit and definite manner in which to define chemical compounds is by structure.

Where, according to the description, structure is essential to determining what subject-matter is useful, this structure must be included in the claims. [See also 17.03.04]

As a matter of clarity, where a biomolecule is defined in terms of its sequence, the claim must define the biomolecule in terms of the sequence listing, and must not simply define "a sequence listing". This latter form could be interpreted as being directed to mere information - *i.e.* to the string of letters of the sequence listing, rather than to the biomolecule.

The fact that a claim explicitly refers to a sequence does not preclude an objection for lack of clarity; for example, in situations where the reference sequence contains a number of variable symbols; *i.e.*, the symbols "Xaa" or "n".

17.07.05*c* Defining families of biomolecules

Uncertainty as to the scope of a claim is often created when families of biomolecules are defined on the basis of vague terminology and variable methods of analysis.[60] As such, it is critical for claims to include, as far as is possible, accurate terminology and the particulars of any analytical methods which may be needed in order to determine the precise limits of the claim.

17.07.05*d* Families of hybridizing nucleic acids

Families of nucleic acids are often defined as sequences which are capable of hybridizing to a particular target sequence under various reaction, or stringency, conditions. Because there is no clear consensus as to what conditions are be used in a given hybridization reaction, and since the use of different reaction conditions will capture different families of nucleic acids, a claim may be held to be indefinite for failing to define the particular parameters to be used during the hybridization reaction and ensuing washings.

A claim which refers to a family of hybridizing nucleic acids may be held to be indefinite if the target nucleic acid itself can be any member of a vast family of nucleic acids; for example, a family of degenerate nucleic acids encoding the same amino acid sequence. In such a case, the number of possible combinations of hybridizing and target nucleic acids becomes astronomically large thus obscuring the scope of the claim.

A claim which suggests that a nucleic acid molecule which hybridizes to a target encoding sequence is itself also capable of encoding a functional polypeptide may be held to be ambiguous since hybridizing nucleic acids, even if they do encode polypeptides, may very well simply encode nonsense polypeptides. For greater clarity, such claims should indicate that the nucleic acid molecule hybridizes to the complement of the target sequence.

17.07.05*e* Nucleic and amino acid terminology

Families of nucleic or amino acid sequences defined by a threshold percentage limit as compared to a target sequence may not be adequately defined if the term "homology" is used since the term implies an evolutionary relationship which either exists or does not exist.[61] Applicants are generally permitted to replace the term "homology" with the term "identity" for greater clarity. The term "similarity" may also be objectionable if there is no clear definition of what the applicant considers to be similar residues.

Families of nucleic or amino acid sequences referred to as being "substantially identical" to a target sequence may not be adequately defined since there is no art accepted convention as to what is encompassed by the term "substantially" and since the scope of a claim may vary depending on what one considers to be a "substantially" identical sequence.

17.07.05*f* Sequence alignment methods

Whenever a sequence is identified as having a certain percent identity (equivalency) to a reference sequence, it is necessary to define in the claim whether the percent identity is relative to the full length of the reference sequence or is a partial alignment (such as a BLAST alignment[62]). If a partial alignment percent identity is intended, it is necessary that the nature of the alignment method be sufficiently described in order to enable the basis of the comparison to be fully appreciated.

Sequence alignment over the full length of the reference sequence is greatly preferred.

17.08 Special topics

This section concerns areas of biotechnology for which particular practices exist and which practices merit particular attention, elaboration or clarification.

17.08.01 Antibodies

Antibodies, as a class of chemical compounds, have been structurally and functionally well-characterized and it is known that, in general, immunization of a mammal with an antigen results in the production of antiserum containing antibodies reactive with the antigen. Antiserum contains a generic family, genus or polyclonal mixture of antibodies where each individual antibody binds to an antigenic determinant or epitope carried on the immunizing antigen. The antiserum is representative of the entire family of antibodies capable of binding to the antigen.

As is the case with claims to any product or process, a claim to an antibody must be supported by a specification which (a) provides a written description of the antibody, and (b) would enable a person of skill in the art to produce the antibody.

17.08.01*a* "Generic" and polyclonal antibodies

Methods for preparing polyclonal sera are well known in the art and a specification need not describe in detail any of these methods to be enabling.

With respect to written description, an antibody, like any other chemical compound, can be described in terms of its chemical structure (polypeptide sequence). However, antibodies are rarely described this way. Indeed, it has become accepted practice to describe antibodies in terms of the antigen to which they bind and claims to antibodies often include functional language such as "capable of binding to". Therefore, a written description of an antibody can be provided by a written description of its antigen binding partner. Since antigens are chemical compounds, the best way to describe an antigen is in terms of its chemical structure. A description in terms of physical or chemical properties may be adequate provided that whatever properties are recited are sufficient to distinguish the antigen from other chemical compounds.

Since an antigen is implicitly understood to carry many epitopes, a written description of the antigen is akin to a written description of the collective of epitopes carried on the antigen and therefore provides a description of the corresponding generic or polyclonal binding partners.

If an application includes a claim to an antigen and a claim to an antibody reactive with the antigen, both claims should be commensurate in scope with respect to the antigen.

If the prior art teaches that antigen X is old, obvious or lacks utility, then antibodies reactive with that antigen would generally be considered obvious or lacking utility. Where the prior art discloses antibodies reactive with a close structural relative of antigen X, then a claim to "an antibody capable of binding to antigen X" may read on the old and known antibody by virtue of cross-reactivity and the claim may therefore be considered to be anticipated.

A claim to "an antibody capable of binding to antigen X" or "a polyclonal antibody capable of binding to antigen X" will generally be considered to be supported by a specification provided:

(i) antigen X itself has been adequately described; and

(ii) either antiserum has been prepared, or where antiserum has not been prepared, there is neither anything peculiar about the antigen nor any indications that would lead a person of skill in the art to question the likelihood of success if that person desired to produce an antibody to the antigen.

Examples:

1. The specification discloses a novel protein isolated from a bacterial pathogen, that has utility as a diagnostic target for detecting disease caused by the bacterium. Further, the specification provides the amino acid sequence (SEQ ID NO: 1) of the protein, methods of purifying it using recombinant techniques, and methods of preparing antibodies to the protein by immunizing a suitable mammalian host. No working examples of an antibody are provided. The protein appears to be a member of a new class of bacterial proteins and a sequence search reveals that the closest structural relative is 20% identical with no common domains of any significance.

Claim:

1. An antibody capable of binding to the protein defined by SEQ ID NO: 1.

Analysis: The claim is acceptable. Since the protein is new, useful as a diagnostic target, and exhibits little structural similarity to known proteins, antibodies prepared against it are likewise, new, useful and unobvious. The specification is both enabling with respect to preparing antibodies and includes a written description (amino acid sequence) of the antigen. The claim is therefore fully supported by the specification.

2. The specification discloses a novel protein isolated from a bacterial pathogen, that has utility as a diagnostic target for detecting disease caused by the bacterium. Further, the specification provides the amino acid sequence (SEQ ID NO: 1) of the protein, methods of purifying it using recombinant techniques, and methods of preparing antibodies to the protein by immunizing a suitable mammalian host. No working examples of a novel antibody are provided. The gene encoding the protein was cloned by immunoscreening a phage library with an old and known antibody reactive with a close homologue of the protein.

Claim:

1. An antibody capable of binding to the protein defined by SEQ ID NO: 1.

Analysis: The claim is objectionable. Despite the fact that the protein defined by SEQ ID NO: 1 itself appears to be novel, the claimed antibody is anticipated since the claim reads on the old and known antibody that has the requisite binding capability, i.e., the antibody used for immunoscreening.

3. The specification discloses a correlation, identified by chromatographic analysis, between a novel hydrophobic peptide and a disease. The amino acid sequence of the peptide is provided and reveals that it is a low-molecular-weight member of a class of peptides to which no known antibodies have ever been prepared despite several attempts. The specification asserts that antibodies to the peptide may be prepared for eventual use in an immunoassay for the disease. The specification does not provide any working examples of an antibody reactive with the peptide.

Claim:

1. An antibody capable of binding to the peptide defined by SEQ ID NO: 1.

Analysis: The claim is objectionable. No antibodies were raised against the novel peptide and the specification teaches that, despite several attempts, antibodies have never been raised against peptides of similar type. A person skilled in the art would not regard the specification as enabling the production of the claimed antibody.

17.08.01*b* Monoclonal antibodies

A monoclonal antibody binds to a specific antigenic determinant or epitope carried on an immunizing antigen. A monoclonal antibody can be viewed as one member of the family of polyclonal antibodies contained in antiserum produced by an immunizing antigen.

As with claims to polyclonal antibodies, a claim to a monoclonal must be supported by a specification that is both enabling and includes an adequate written description of the antibody.

The core steps for preparing monoclonal antibodies are now well-known and established. Thus, for a specification to be enabling, the polypeptide antigen against which the monoclonal is raised must be described but an applicant need not set out a detailed procedure for producing the antibody. A detailed step-by-step protocol would only be necessary if the invention resides, at least in part, in an applicant having adapted known procedures to overcome some difficulty in making a monoclonal to a particular antigen.

An examiner will consider the following when determining whether a specification is enabling with respect to monoclonal antibodies:

(1) whether the applicant actually prepared a monoclonal antibody;
(2) where a monoclonal antibody has not been prepared,

(i) whether the antigen and core steps for preparing the monoclonal are described,
(ii) the availability and/or ease of production of the antigen,
(iii) whether there are indications that the applicant was unable to produce a monoclonal antibody or to suggest that one of skill in the art would not be able to reproducibly make a monoclonal to the subject antigen,
(iv) whether there are indications which suggest that undue experimentation or undue adaption of known core steps would be necessary for preparing a monoclonal.

The foregoing list is non-exhaustive and non-cumulative and is intended as a guide only. Each application will be considered on its own merits.

A specification must not only be enabling with respect to a claimed monoclonal antibody but also must provide a written description of the antibody. The written description requirement is satisfied where a specification describes at least one monoclonal and it is evident that the applicant was in possession of the antibody at the time the patent application was filed. Reference to a biological deposit of either a hybridoma or a monoclonal antibody is the best way to demonstrate possession.

Applicants should note however, that a deposit for patent purposes, i.e., for consideration in determining whether or not subsection 27(3) of the *Patent Act* has been complied, must be in accordance with sections 104 to 106 of the *Patent Rules*.

An adequate written description of a monoclonal antibody can also be provided by an explicit description of the epitope to which it binds in the same way as a written description of a generic antibody or polyclonal can be provided by a general description of an antigen. As discussed in section 17.08.01*a*, a written description of the antigen amounts to a written description of the collective of epitopes carried on the antigen and therefore provides a description of the family of polyclonal binding partners. Since a monoclonal is one member of the family which binds to a specific epitope, if it is to be described in terms of its binding partner, the specification must include a structural description of the epitope.

An epitope on a protein can be described in terms of a specific amino acid sequence which is a subset of the complete polypeptide sequence of the protein, or as a binding pocket defined by specific non-contiguous amino acids.

Where existence of an epitope has not been demonstrated but rather is predicted, for example by computer modelling, a specification must disclose not only a structural description of the epitope, but also a factual basis and sound line of reasoning to support the prediction of a putative antibody binding site.

An examiner will consider the following when determining whether a specification provides a written description with respect to monoclonal antibodies:

(1) whether the applicant was in physical possession of a monoclonal antibody at the time of filing;

(2) whether the applicant had made a deposit of a hybridoma or monoclonal antibody for patent purposes or was in a position to do so at the time of filing;

(3) whether there is specific structural description of an epitope or epitopes carried on the antigen to which the monoclonal will bind.

The foregoing list is non-exhaustive and non-cumulative and is intended as a guide only. Each application will be considered on its own merits.

Where the prior art discloses a monoclonal antibody specific for antigen X, a broad claim would not be acceptable as it would read on the prior art.

A prior art document which merely describes how a monoclonal antibody to an antigen might be prepared yet does not specifically describe such a monoclonal antibody, is not considered an anticipatory document against an application that claims and specifically describes a monoclonal antibody.

Example:

1. The specification discloses a novel isolated protein from a bacterial pathogen that has utility as a diagnostic target for detecting disease caused by the bacterium. Further, the specification provides the amino acid sequence (SEQ ID NO: 1) of the protein, methods of purifying it using recombinant techniques as well as methods of preparing monoclonal antibodies to the protein by using traditional techniques. The specification describes neither an actual monoclonal antibody, nor a paratope thereof, nor a specific epitope of the protein.

Claim:

1. A monoclonal antibody capable of binding to the peptide defined by SEQ ID NO: 1.

Analysis: The claim is objectionable. Although the specification is enabling with respect to preparing a monoclonal antibody capable of binding to the antigen, there is no written description of such a monoclonal. The specification does not disclose that the applicant was in possession of a monoclonal antibody nor does it disclose a structural description of a specific epitope where a putative monoclonal antibody would bind.

Appendix 1 - Deposits of biological material

For the purposes of section 38.1 of the *Patent Act*, the term "biological material" includes material which is capable of direct or indirect self-replication. Directly self-replicating biological materials are those that replicate by themselves. Indirectly self-replicating biological materials are those that are capable of replication only in association with a directly self-replicating biological material. Bacteria, fungi (including yeast), cells in culture and hybridomas are representative examples of directly self-replicating materials; indirectly self-replicating materials include nucleotide sequences, plasmids, vectors, viruses, phages and replication-defective cells.

The Budapest Treaty

The *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* (The *Budapest Treaty*) was established in 1977. The Treaty is administered by WIPO and obliges contracting states to recognize the fact and date of a deposit of biological material for patent purposes, when it is made in a depositary which has acquired official status under the Treaty. Such a depositary is known as an International Depositary Authority (IDA). An applicant who is making multiple patent filings need only make one IDA deposit to satisfy the deposit practice in all contracting states.

The term “microorganism” is not defined in the Treaty so that it may be interpreted in a broad sense as to the applicability of the Treaty to microorganisms to be deposited under it. Whether an entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it. Thus, for example, tissue cultures and plasmids can be deposited under the terms of the Treaty, even though they are not microorganisms in the strict sense of the word.

The *Budapest Treaty* came into force, with respect to Canada, on September 21, 1996.

Where to make a deposit

A list of International Depositary Authorities and their specific requirements is available at the following site:

http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/pdf/idalist.pdf

When to make a deposit

In accordance with subsection 104(1) of the *Patent Rules*, a deposit of biological material with an international depositary authority must be made on or before the filing date of the application.

Identifying a deposit

In accordance with subsections 104(2) and 104(3) of the *Patent Rules*, the applicant must inform the Commissioner, prior to publication of the application, of the name of the IDA and the accession number given by the IDA to the deposit, and must include that information in the description. Further, in accordance with section 104.1 of the *Patent Rules*, the applicant must include in the description the date of the original deposit with the IDA.

Term of deposit

When a sample of biological material is deposited in an IDA under the *Budapest Treaty* for the purposes of patent protection, the depositor undertakes not to withdraw the sample for a period of at least 30 years from the date of deposit and for at least five years from the date of the most recent request made to the depositary for the furnishing of a sample of the deposited material (Rules 6 and 9 of the Regulations under the *Budapest Treaty*).

New and substitute deposits

After an original sample of biological material has been deposited in an IDA (an original IDA deposit), circumstances may necessitate that a new sample of the same material be deposited in either the same or a different IDA (Article 4 of the *Budapest Treaty*) or that the sample be transferred to a substitute IDA (Rule 5 of the *Regulations Under the Budapest Treaty*).

If an IDA cannot furnish a sample of deposited material because it is no longer viable, a depositor must make a new deposit in the same IDA.

If an IDA cannot furnish a sample of deposited material because the sample must be sent abroad and this is prevented by export or import restrictions, a depositor may make a new deposit in another IDA.

To maintain an original IDA deposit date, a new deposit must be made within three months of the depositor receiving notice from an IDA that a sample is no longer viable or cannot be sent abroad, or that the IDA's status has changed. The deposit must be accompanied by a statement that the newly deposited material is the same as that originally deposited. Under subsection 106(2) of the *Patent Rules*, if a new deposit is not made in accordance with Article 4 of the *Budapest Treaty*, the application is treated as if no deposit had ever been made.

If an IDA temporarily or permanently discontinues any of the tasks required of it as an IDA such that samples of deposited biological material can no longer be provided, the defaulting IDA is required to transfer samples of deposited materials to another IDA. The new IDA is referred to as a substitute IDA and the deposit is known as a substitute deposit.

In accordance with section 105 and subsection 106(1) of the *Patent Rules*, whenever a deposit of a biological material is made (or transferred) to an IDA different from the original IDA, the applicant must inform the Commissioner of the name of the new IDA and of the accession number given by the new IDA to the deposit before the expiry of the three-month period after the date of issuance of a receipt by that IDA.

Access to deposited biological material

Deposited biological material becomes available to the public once a patent application is open to inspection under section 10 of the *Patent Act,* or for applications filed before October 1, 1989 once a patent issues.

In accordance with subsection 104(4) of the *Patent Rules*, an applicant is entitled to restrict access to a deposit of biological material until such time as a patent has issued, or the application is refused, abandoned and no longer subject to reinstatement, or withdrawn. In such cases, any person may request that an independent expert be nominated by the Commissioner in accordance with subsection 109(1) of the *Patent Rules.* Once so nominated, that expert will have access to the deposit in accordance with subsection 104(4) of the *Patent Rules*.

In order to access a deposited biological material, a request must be made. Where a restriction has been made by the applicant and is in effect, only the independent expert may make such a request. When such a restriction is not in place, or no longer applicable, any person may request access to the deposited material.

A request for a sample of the biological material must be submitted to the Commissioner of Patents and requires, inter alia, that the requester undertake in accordance with section 108 of the *Patent Rules* not to make the sample, or any culture derived from the sample, available to any other person nor to use the sample, or any culture derived from the sample, for any purpose other than experiments that relate to the subject-matter of the application until such time as a patent issues, or the application is refused, abandoned and no longer subject to reinstatement, or withdrawn.

In the case of a granted patent, the request for a sample of the deposited material may be made directly to the IDA, without the need to provide a request form certified by the

Commissioner of Patents unless the IDA specifically requires that a certified request form indicating that the patent has been issued be submitted.

A request form for the furnishing of a sample of deposited material will be published from time to time in the Canadian Patent Office Record (CPOR) and is also provided on-line at:

http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/guide/pdf/app3_budapest_forms.pdf.

Detailed procedures for obtaining samples of biological materials are provided in appendix 2.

Nomination of an independent expert

In accordance with subsection 109(1) of the *Patent Rules*, the Commissioner of Patents will nominate an independent expert with the agreement of the applicant. Both the applicant and the person requesting that an expert be nominated may make suggestions as to who would be a suitable expert. In the event that the Commissioner of Patents and the applicant cannot agree on an acceptable expert within a reasonable time after a request has been made that such an expert be nominated, the applicant's notice under subsection 104(4) of the *Patent Rules* that access to a deposit be restricted to an expert is deemed, in accordance with subsection 109(2) of the *Patent Rules*, never to have been filed.

Certification

After a request has been filed with the Commissioner of Patents for the furnishing of a sample of deposited biological material, the Commissioner will, in accordance with subsection 107(2) of the *Patent Rules*, make the certification referred to in Rule 11.3(a) of the *Regulations Under the Budapest Treaty* that the deposit is referred to in an application for patent in Canada, that the requester has fulfilled all conditions for the furnishing of a sample, and that the requester has a right to a sample of the deposited material.

A copy of the request along with the certification is then sent to the requester in accordance with subsection 107(3) of the *Patent Rules* or in the case where the requester is an independent expert, to the applicant and to the person who requested the nomination of the expert in accordance with subsection 110(2) of the *Patent Rules*.

Appendix 2 - Steps for obtaining samples of biological materials

To obtain a sample of a biological material referred to in a pending application on which no restriction has been placed under section 104(4) or 160(4) of the *Patent Rules*:

(i) the requesting party completes parts I through IV of the request form;
(ii) the requesting party prepares a letter of undertaking, agreeing to abide by the conditions set out in section 108 or 164 of the *Patent Rules*;
(iii) the requesting party, under a covering letter, sends the letter of undertaking and the request form to the Commissioner of Patents, Place du Portage I, 50 Victoria St., Gatineau, Canada, K1A 0C9;
(iv) the Commissioner, or a designate, completes part V of the request form, certifies it with the seal of the Patent Office and returns it to the requesting party under a covering letter;
(v) the requesting party sends the request form, a purchase order and any fee required to the IDA;
(vi) the IDA sends a sample of the biological material to the requesting party.

To release a sample of a biological material referred to in a pending application, on which a restriction has been placed under section 104(4) or 160(4) of the *Patent Rules,* to an independent expert:

(i) the requesting party requests that the Commissioner of Patents nominate an independent expert for the purposes of the application;
(ii) the Commissioner of Patents, with the agreement of the applicant, nominates an independent expert within a reasonable time;
(iii) the independent expert completes parts I through IV of the request form;
(iv) the independent expert prepares a letter of undertaking, agreeing to abide by the conditions set out in section 108 or 164 of the *Patent Rules*;
(v) the independent expert, under a covering letter, sends the letter of undertaking and the request form to the Commissioner of Patents, Place du Portage I, 50 Victoria St., Gatineau, Canada, K1A 0C9;
(vi) the Commissioner, or a designate, completes part V of the request form, and certifies it with the seal of the Patent Office;
(vii) the Commissioner sends, under covering letters, the completed request form to the requesting party, and a copy of thereof to the applicant;
(viii) the requesting party sends the request form, a purchase order and any fee required to the IDA;
(ix) the IDA sends a sample of the biological material to the independent expert.

To obtain a sample of a biological material referred to in an issued patent:

(i) the requesting party writes to the IDA with a purchase order giving the name

and address of the requesting party;
(ii) the order should include evidence, *e.g.* a copy of the cover page of the Canadian patent, indicating that the patent has issued and the accession number of the biological material desired;
(iii) where required, the fee charged by the IDA for furnishing the sample is submitted along with the order.

Endnotes for Chapter 17

1. *Re Application of Abitibi Co.* [(1982) C.D. 933, 62 C.P.R. (2nd), 81 (P.A.B.)]

2. *Harvard College v. Canada (Commissioner of Patents)* [2002] SCC 76; [(2002), 21 C.P.R. (4th), 417 (S.C.C.)]

3. *Office Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues* C.P.O.R. Vol. 134, No. 25, June 20, 2006

4. *Monsanto Canada Inc. v. Schmeiser* [2004] SCC 34; [(2004), 31 C.P.R. (4th), 161 (S.C.C.)] at paragraph 17

5. *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] S.C.R. 1623 [(1989), 25 C.P.R. (3rd), 257(S.C.C.)] at pages 263-265 (cited to C.P.R.)

6. *Tennessee Eastman v. Commissioner of Patents* [(1972), 8 C.P.R. (2nd), 203 (S.C.C.)]; *Imperial Chemical Industries Ltd. v. Commissioner of Patents* [(1986), 9 C.P.R. (3rd), 289 (F.C.A.)]

7. This conclusion is inferred from the decision in *Re Application 319,105 of Boehringer Mannheim G.m.b.H.* (1987) C.D. 1108, allowing a diagnostic method involving the removal of blood from the body

8. *Re Application 394,006 of Catheter Technology Corporation* (1986) C.D. 1082

9. *Re Application No. 532,566 of General Hospital Corporation* (1996) C.D. 1209; *Re Application No. 559,960 of Senentek* (1997) C.D. 1213

10. *Re Application No. 003,389 of N.V. Organon* [(1973) C.D. 144, 15 C.P.R. (2nd), 253 (P.A.B.)]; *Re Application for Patent of Goldenberg* [(1988) C.D. 1119, 22 C.P.R. (3rd), 159 (P.A.B.)]

11. *Re Application No. 862,758* (1970) C.D. 33; *Re Application No. 954,851 of Biehl* (1971) C.D. 63

12. *Axcan Pharma Inc. v. Pharmascience Inc.*, [2006] FC 527 [(2006), 50 C.P.R. (4th), 321 (F.C.)]

13. *Re Application No. 003,772 of Ijzerman* (1975) C.D. 254; *Merck & Co. v. Apotex Inc.* [2005] FC 755 [(2005), 41 C.P.R. (4th), 35 (F.C.)]

14. *Goldenberg* (supra at 10)

15. *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at page 160 citing *Halsbury's Laws of England* (3rd ed.), vol. 29 at page 59

16. *Re Application of Abitibi Co.* [(1982) C.D. 933, 62 C.P.R. (2nd), 81 (P.A.B.)]

17. *Re Application No. 003,389 of N.V. Organon* [(1973) C.D. 144, 15 C.P.R. (2nd), 253 (P.A.B.)]; the criteria "controllable and reproducible by the means disclosed" were commented on by the Federal Court of Appeal in *Harvard College v. Canada (Commissioner of Patents)* [(2000), 7 C.P.R. (4th), 1 (F.C.A.)] at paragraph 70 (page 26); it was clarified at paragraph 75 that these requirements pertain only to those features necessary to achieve the objects of the invention.

18. *Apotex Inc. v. Wellcome Foundation Ltd.* [2002] SCC 77 [(2002), 21 C.P.R. (4th), 499 (S.C.C.)] at paragraph 46

19. *Apotex* (supra at 18) at paragraph 70

20. *Pfizer Canada Inc. v. Apotex Inc.* [2007] FC 26 [(2007), 59 C.P.R. (4th), 183 (F.C.)] at paragraph 70; aff'd [2007] FCA 195 [(2007), 60 C.P.R. (4th), 177 (F.C.A.)]

21. The Office's interpretation of *Apotex* (supra at 18) as regards proper disclosure has recently been confirmed in *Eli Lilly Canada Inc. v. Apotex Inc.* [2008] FC 142 at paragraph 164.

22. *Aventis Pharma Inc. v. Apotex Inc.* [2005] FC 1283 [(2005), 43 C.P.R. (4th), 161 (F.C.)] at paragraphs 93 and 164; aff'd [[2006] FCA 64 [(2006), 46 C.P.R. (4th), 401 (F.C.A.)] at paragraph 30

23. *Monsanto Co. v. Commissioner of Patents* [(1979), 42 C.P.R. (2nd), 161 (S.C.C.)]

24. *Radio Corporation of America v. Raytheon Manufacturing Co.* [(1957), 27 C.P.R. (1st), 1 (Ex.Ct.)] at page 14

25. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)] at page 111; the cited passage has been referred to more recently in, e.g., *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.* [2001] FCT 889 [(2001), 13 C.P.R. (4th), 193 (F.C.T.D.)] (rev'd on other grounds) and *671905 Alberta Inc. v. Q'Max Solutions Inc.* [2001] FCT 888 [(2001), 14 C.P.R. (4th), 129 (F.C.T.D.)] (varied [(2003), 27 C.P.R. (4th), 385 (F.C.A.)]). *Minerals Separation* was referred to in both *Consolboard* (supra at 15) at page 157 and *Pioneer Hi-bred* (supra at 5) at page 268 as in a general sense setting out the requirements of a sufficient disclosure.

26. *Consolboard* (supra at 15) at pages 154 to 155, Dickson J. quoting H.G. Fox from his *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.]

27. *Consolboard* (supra at 15) at page 157

28. *Minerals Separation* (supra at 25) at page 111; this passage endorsed in *Consolboard* (supra at 15) at page 157

29. *Pioneer Hi-Bred* (supra at 5) at page 271

30. *Abitibi* (supra at 16); *Re Application No. 291,870 of Connaught Laboratories* (1982) C.D. 962

31. Little jurisprudence of direct relevance to biotechnology exists on point. Consider, however, the conclusions reached in *Re Institut Pasteur Patent Application* [(1995) C.D. 1206, 76 C.P.R. (3rd) 206], *Re Application No. 610,944 of Alonso* (2006) C.D. 1269, and *Re Application No. 471,056 of Research Corporation* (1992) C.D. 1171. In *Pasteur*, claims to a hybridoma and to a monoclonal antibody were refused because these species were deemed not to be adequately described - no example of a successfully prepared hybridoma or monoclonal antibody having been provided. In comparison, in *Alonso* and *Research Corporation* a number of examples of prepared hybridomas or mutant oyster setting bacteria were considered to provide a proper description of the claimed subject-matter.

32. *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* [2008] SCC 61 at paragraphs 24-27 and 33-37

33. *Reeves Bros. v. Toronto Quilting* [(1978), 43 C.P.R. (2nd), 145 (F.C.T.D.)]

34. *Beloit Canada Ltd. v. Valmet* Oy [(1986), 8 C.P.R. (3rd), 289 (F.C.A.)]

35. *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraph 28. Although the Supreme Court was here only referring to the decision in *Beloit*, the same conclusion would seemingly apply to the earlier guidance in *Reeves Bros.*

36. *Diversified Products v. Tye-Sil* [(1991), 35 C.P.R. (3rd), 350 (F.C.A.)]

37. *Apotex v. Sanofi-Synthelabo* (supra at 32); *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.* [2002] FCA 158 [(2002), 17 C.P.R. (4th), 478 (F.C.A.)]

38. *Abbott Laboratories v. Canada (Minister of Health)* [2006] FCA 187 at paragraphs 23 to 25; *Calgon Carbon Corporation v. North Bay (City)* [2006] FC

1373 [(2006), 41 C.P.R. (4th), 78 (F.C.)] at paragraphs 114 to 136

39. *Astrazeneca AB v. Apotex Inc.* [2007] FC 688 [(2007), 60 C.P.R. (4th), 199 (F.C.)] at paragraphs 50-53

40. *Hoffmann-LaRoche & Co. Ltd. v. Commissioner of Patents* [(1955), 23 C.P.R. (1st), 1 (S.C.C.)]

41. *Janssen-Ortho Inc. v. Novopharm Limited* [2006] FC 1234 [(2006), 57 C.P.R. (4th), 6 (F.C.)] at paragraphs 99, aff'd [2007] FCA 217 [(2007), 59 C.P.R. (4th), 116 (F.C.A.)]. The requirement of s.28.3 has been variously described by the courts as one of "ingenuity", "inventive ingenuity", "invention", "inventiveness", and "non-obviousness". These terms can be used more or less interchangeably to describe the requirement codified in s.28.3.

42. *Janssen-Ortho* (supra at 41) at paragraphs 109-110; *Canamould Extrusions Ltd. v. Driangle Inc.* [2003] FCT 244 [(2003), 25 C.P.R. (4th), 343 (F.C.T.D.)] at paragraph 61 (rev'd on other grounds); *Baker Petrolite* [2001] FCT 889 [(2001), 13 C.P.R. (4th), 193 (F.C.T.D.)] at paragraphs 94-96 (rev'd on other grounds, see supra at 33); *Harvard College v. Canada (Commissioner of Patents)* [2000] 4 F.C. 528 [(2000), 7 C.P.R. (4th), 1 (F.C.A.)] at paragraph 28 (rev'd on other grounds, see supra at 2)

43. *Beloit* (supra at 34) at page 293

44. *Diversified Products* (supra at 36) at page 366

45. *The King v. Uhlemann Optical Co.* [1952] 1 S.C.R. 143 at paragraph 19 [(1951), 15 C.P.R. (1st), 99 (S.C.C.)] at pages 104-105; *Wandscheer v. Sicard Ltd* [1948] S.C.R. 1 [(1947), 8 C.P.R. (1st), 35 (S.C.C.)] at page 48; both case citing *Samuel Parkes & Co. v. Cocker Bros. Ltd.* 46 R.P.C. 241 at page 248.

46. *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraphs 61-64; *Janssen-Ortho Inc. v. Novopharm Limited* [2007] FCA 217 [(2007), 59 C.P.R. (4th), 116 (F.C.A.)] at paragraph 25. In *Sanofi-Synthelabo*, the Supreme Court refers at paragraph 67 to a general 4-step approach that may be used in framing the inquiry.

47. *Janssen-Ortho Inc. v. Novopharm Limited* [2006] FC 1234 [(2006), 57 C.P.R. (4th), 6 (F.C.)] at paragraph 113, aff'd [2007] FCA 217 [(2007), 59 C.P.R. (4th), 116 (F.C.A.)] at paragraph 25

48. *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraphs 59-69, especially at 59, 64, 68 and 69

49. *Beloit* (supra at 34) at page 294; for the purposes of examination, the term "patent" must be understood to mean "application".

50. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1949), 12 C.P.R. (1st), 102 (S.C.C.)] at pages 199, 203 to 204, and 218 citing *Natural Colour Kinematograph Co. v. Bioschemes Ltd.* 32 R.P.C. 256 at pages 266 and 269; *Free World Trust v. Électro Santé Inc.* [2000] SCC 66 [(2000), 9 C.P.R. (4th), 168 (S.C.C.)] at paragraphs 41 to 43

51. *I.G. Farbenindustrie A.G.'s Patents* [(1930), 47 R.P.C. 289] at pages 322 to 323

52. The *Farbenindustrie* criteria appear to have been endorsed at least as early as 1947 in *Minerals Separation* (supra at 25 at pages 163 to 164) and were affirmed by the Supreme Court in *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraph 9.

53. *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraph 9; *I.G. Farbenindustrie* (supra at 51) at page 321

54. *Pfizer Canada Inc. v. Canada (Minister of Health)* [2006] FCA 214 [(2006), 52 C.P.R. (4th), 241 (F.C.A.)] at paragraph 31; *I.G. Farbenindustrie* (supra at 51) at page 323

55. *Re Application 2,017,025 of Yeda Research and Development Corporation* (2007) C.D. 1273

56. *Free World Trust* (supra at 50) at paragraph 32

57. *Natural Colour Kinematograph* (supra at 50) at page 266; this passage also cited in *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1952), 15 C.P.R. (1st), 133 (P.C.)]

58. Any such amendment, of course, must not introduce new subject-matter such as to contravene subsection 38.2(2) of the *Patent Act*.

59. *Natural Kinematograph* (supra at 50) at page 266. The use of "ambiguous" in this context should be understood in the context of the entire passage, wherein it was earlier stated that a patent is invalid if it relies on "language which, when fairly read, is avoidably obscure or ambiguous".

60. Dufresne, Guillaume and Duval, Manuel, "Genetic sequences: how are they patented?" (2004), 22 Nature Biotechnology 231; Yoo, Heahyun *et al.*, "Intellectual Property Management of Biosequence Information from a Patent Searching Perspective" (2005), 27 World Patent Information 203

61. Reeck, Gerald *et al.*, " 'Homology' in proteins and nucleic acids: A terminology muddle and a way out of it" (1987), 50 Science 667

62. Altschul, S. *et al.*, "Basic Local Alignment Search Tool" (1990), 215 Journal of Molecular Biology 403

Chapter 18

Protests and filing of prior art

18.01 Filing prior art

Under section 34.1 of the *Patent Act*, any person may file prior art with the Commissioner. This prior art can consist of patents, applications for patents open to public inspection, or publications that the person believes have a bearing on the patentability of any claim in a patent application. Prior art filed with the Commissioner under section 34.1 of the *Patent Act* must be accompanied by an explanation of why the art is pertinent. If the application referred to by the person submitting the prior art is a PCT application which has not yet entered the national phase in Canada, the Canadian Patent Office will retain the submission until the last date for late national entry in Canada has expired.

When prior art is received under the provisions of section 34.1 of the *Patent Act*, the provider is notified that the filing of prior art has been received, but the provider will not be informed regarding the action taken thereon [1] . The prior art material is made part of the file of the application and the applicant of that application is notified that a submission of prior art has been made. The prior art is only considered by the examiner after a request for examination has been received. The normal prosecution, including allowance of applications, continues despite the submission of a filing of prior art [2], unless sufficient grounds are presented to warrant action based on this filing of prior art.

When there is no prior art listed or when there is no explanation of why the art is pertinent, in a "filing of prior art" letter, this letter is then treated and considered as a protest.

18.02 Protests

In accordance with section 10 of the *Patent Rules*, any written communication made to the Commissioner with the stated or apparent intention of protesting against the granting of a patent is acknowledged by the Commissioner. The protestor will not be informed regarding the action taken thereon[1]. However a protestor may have access to the prosecution file of the application at the time of opening to public inspection. When the information is available during the pendency of an application, a protest provides an adequate alternative remedy that should be exhausted by a competitor before seeking judicial review [3].

Protests may develop as a result of public inspection of opened applications. A protest may also develop as a result of a search request under section 11 of the *Patent Act* by means of which the protestor has discovered that there is a pending application that corresponds to a foreign patent. In these cases the protestor should identify the Canadian patent publication number (if following a public inspection of opened applications), or the foreign patent publication (if following a request under section 11 of the *Patent Act*). Any protest that fails to identify an application by number, inventor or applicant reduces the likelihood of the Commissioner locating the application and therefore reduces the effectiveness of the protest.

Each time a protest is received, the Patent Office carries out a search to identify or to confirm (when the application(s) is/are identified by the protestor) the application(s) to which the protest applies. If the application(s) is/are found, the protest is made part of the file of the application and therefore when the file is opened any action taken on the protest is also available. A notification that a protest has been received in the Patent Office will be sent to the applicant of any application against which a protest is made. The protestor will also be advised of the receipt of the protest in the Patent Office (the application number will not be Disclosed if this application is not already opened for public inspection). When the specific application cannot be located (e.g. when the application has not already been filed at the Patent Office or when there is not enough information in the protest to identify the application), the protest is classified in its most relevant class(es), unless the application is located before being brought to the examiner. The examiner keeps the protest for two years.

If the protestor wishes to submit further details or another protest, he/she is welcome to do so, but each time the protestor will only receive a notice of acknowledgment. The examiner will not discuss the prosecution of the application(s) with the protestor. The normal prosecution, including allowance of applications, continues despite the submission of a protest unless sufficient grounds are presented to warrant action based on the protest.

18.03 Affidavits

Affidavits containing allegations not backed by dated documentation will usually not be sufficient reason for the Commissioner not to grant the patent. The affidavits may however contain information that could raise serious reasons as to why a patent should not be granted or lead to documentation that could be very pertinent. Someone who submits affidavits should support his/her allegations with dated material or give details to locate such material.

18.04 Applying protests or filing of prior art

A protest or a filing of prior art is only considered by the patent examiner after the request for examination is received. Information in a protest or a filing of prior art is taken into account by the examiner, and if it provides sufficient grounds for objection, it will be cited. In the event that the application has previously been allowed by the examiner but has not yet been issued, the pertinence of the protest or of the filing of prior art will determine whether the notice of allowance will be withdrawn. If further action is required in view of the protest or of the filing of prior art, the application will be returned to the examiner. See chapter 13 for more information on notice of allowance and withdrawal thereof.

18.05 Protests or filing of prior art and confidentiality

Any protest or filing of prior art will become part of the opened application file (available to the public), therefore, any protest or filing of prior art requesting confidentiality will be returned to the sender. Information supplied in such a confidential document will not be considered by the patent examiner.

Endnotes for Chapter 18

[1] Section 10 of the *Patent Rules*: "... no information shall be given as to the action taken".

[2] Monsanto Company *et al.* v. Commissioner of Patents *et al.* (1999), 1 C.P.R. (4th) 500 at 511 *"...Notice of Allowance is not a decision subject to judicial review either by the applicant or a third party."*

[3] Pharmascience Inc. v. Commissioner of Patents *et al.* (1998), 85 C.P.R. (3d) 59 at 66, affirmed 5 C.P.R. (4th) 428

Chapter 19

Amendments to patent applications

19.01 Submission of amendments by the applicant

Applicants may amend their applications either on their own initiative or in response to an examiner's requisition. The amendment must comprise new or replacement pages for any changes made to the application and a supporting explanation as described in sections 19.02.02 and 19.02.03, below. It is strongly recommended that the template, as outlined in section 19.02.04 below, be followed.

19.01.01 Signature on the amendment

Under subsection 6(1) of the *Patent Rules*, an amendment must be signed by the authorized correspondent. In this regard, please refer to sections 4.02 and 4.03 of MOPOP regarding the appointment of agents and representatives.

The patent agent's signature, the firm's seal or stamp, a covering letter with the official letterhead or a mark recognized by the Patent Office to identify the firm will be accepted as a signature for an authorized correspondent who is a patent agent or an associate patent agent practitioner in a firm listed in the patent agent register. For other authorized correspondents (that is, an inventor, assignee, representative), the paper copy of the amendment must be signed, although a copy or an image of the signature on a fax or an electronic image is acceptable.

When an amendment is filed by a person or firm other than by the authorized correspondent on file at the Patent Office, this person or firm will be notified by office letter to request an appointment or revocation of agent or representative properly signed by the applicant. The amendment will be entered only after such an appointment or revocation is received. If the amendment follows an examiner's report or an office letter, this appointment or revocation must be submitted prior the due date in order to avoid abandonment of the application.

When an amendment is submitted along with, or following, a recent appointment or revocation of agent or representative, an opening sentence should be incorporated on the first page of the amendment to indicate that an appointment or revocation form is being concurrently filed, or has been recently filed.

19.02 Form of amendments

Under subsection 8(1) of the *Patent Rules*, communications addressed to the Commissioner in relation to a patent application must relate to one application only; however, several actions with respect to one application can be combined in the same communication. Communications regarding amendments, the appointment or revocation of agents and the payment of fees should be incorporated in the same letter using uppercase headings to introduce each action (see section 19.02.04 on Suggested Templates for Amendments).

Amendments to the application are made by inserting new pages or replacing existing pages altered by the amendments (section 34 of the *Patent Rules*). New pages must be supplied for all affected pages, irrespective of whether the changes are for adding or deleting matter.

For applications filed after October 1, 1996, all pages altered by the amendment must meet the criteria of sections 68 to 70 of the *Patent Rules* with respect to documentation presentation, section 73 of the *Patent Rules*, with respect to the numbering of pages and section 85 of the *Patent Rules,* with respect to the numbering of claims. It should be noted that while claims must be numbered consecutively in Arabic numerals, page numbers may take any form provided that they are consecutive. For example, the sequence 1, 2, 3, 3A, 3B, 4 would be acceptable for page numbering, especially when pages are inserted. If pages are deleted, the applicant can renumber the description to keep the numbering in sequence. Alternatively, the applicant may submit obliterated pages by an oblique line, which are appropriately numbered, to replace the deleted pages.

For applications filed in the period beginning on October 1, 1989 and ending on the day before October 1, 1996, all pages altered by the amendment must meet the criteria set out in sections 133 and 135 of the *Patent Rules.*

For applications filed before October 1, 1989, all pages altered by the amendment must meet the criteria of sections 169 and 171 of the *Patent Rules.*

Under subsections 71(3), 136(3) and 172(3) of the *Patent Rules*, the text matter of the abstract, the description, the drawings and the claims shall be wholly in English or wholly in French. However, the response can be filed in the other Canada official language provided that the text matter of the application and the amendments are wholly in English or wholly in French. The Patent Office will communicate with the applicant using the official language of the application, unless the applicant indicates in the response that he or she prefers to receive future communications in the other official language.

Amendments requested to take effect at some time in the future (delayed amendment), are not permitted by the Patent Office.

19.02.01 Supporting explanation

Under section 34 of the *Patent Rules,* every amendment made to an application must be accompanied by a written statement in a covering letter explaining the nature and purpose of the amendment.

If the amendment is in response to an examiner's requisition identifying defects in the application, the written statement must explain the manner in which the amendment overcomes the defects. If this statement is not provided, the Patent Office enters the amendment (except as described in 19.07 below) and the applicant is requisitioned by the examiner to provide the necessary information within a specified time limit. Where possible, the Patent Office indicates the type of information which, if it were supplied, would satisfy the requirements of section 34 of the *Patent Rules*.

The written statement must also provide complete instructions for entering the amendment into the application by specifying how pages are to be cancelled, inserted or replaced. If the instructions are vague or incomplete, the amendment will not be entered into the application file and the Patent Office will requisition clearer instructions by office letter within a specified time limit.

19.02.02 Entry of new pages into the application file

Generally, when an amendment is received in the Patent Office, it is entered into the application file before an examiner determines its acceptability. New pages submitted by the applicant are substituted in place of the pages altered by the amendment and the covering letter with the supporting explanation for the amendment is attached to the file.

It should be noted that the entry of new pages into the application file does not denote acceptance of the amendment by the examiner.

19.02.03 Amendments to very large applications

Applications containing more than 1000 pages are considered to be very large applications.

The Patent Office requires that amendments regarding an application which was originally filed on CD-ROM has to be submitted on CD-ROM in duplicate. The CD-ROM must include a revised copy of the entire application with instructions in the covering letter filed in conjunction with the amendment describing the changes that were made.

The acceptable formats for graphic images are listed in section 5.03.02 of MOPOP and in the CPOR Notice dated December 28, 1999 (CPOR Vol. 127 No. 52, Notice No. 20).

19.02.04 Suggested templates for amendments

Under section 7 of the *Patent Rules*, communications addressed to the Commissioner in relation to an application must include:

- the name of the applicant or inventor;
- the application number, if one has been assigned by the Patent Office; and
- the title of the invention.

Further, it is recommended that the filing date and the classification, if known, be identified on the amendment. This information is useful to validate the application number.

It is also recommended that one of the following headers in uppercase be used to identify the nature of the amendment, as applicable:

- VOLUNTARY AMENDMENT
- VOLUNTARY AMENDMENT FOLLOWING PCT NATIONAL ENTRY
- AMENDMENT/REMARKS AFTER EXAMINER'S REPORT
- AMENDMENT/REMARKS AFTER OFFICE LETTER
- VOLUNTARY SUBMISSION

The response should begin with all the instructions for entering the amendment(s) into the application, followed by any remarks. The instructions should be divided by clear headings representing each section of the patent application addressed such as the abstract, description, claims and drawings for each section of the patent application. Since the applicant may need to address several requisitions, distinct headings in the remarks for each requisition are advisable.

When an amendment is combined with other matters in the same letter, a heading for each matter in uppercase should introduce the matter, and all the different matters should be listed in uppercase on the first page of the letter, such as:

Voluntary Amendment
Appointment and Revocation of Agent
Request for Examination
Maintenance Fee

For applications filed after October 1st, 1996, according to paragraph 68(1)*(a)* of the *Patent Rules,* documents filed in connection with the patent application, including amendments, must be on sheets of good quality white paper that are free of creases and folds and that are in letter format (21.6 cm x 27.9 cm) or in A4 format (21 cm x 29.7 cm).

For applications filed before October 1st, 1996, according to sections 133 or 169, amendments must be presented clearly and legibly on sheets of good quality white paper, which shall not be more than 21.6 cm by 33 cm (8½ inches by 13 inches).

However, letter format and A4 format are preferred. Images attached to an electronic filing of amendments/remarks must be submitted in letter or A4 format.

19.03 Types of Amendments

Amendments may be submitted by the applicant either voluntarily or in response to an examiner's requisition. The procedures followed by the Patent Office to process an amendment depend on the status of the application file, for example, whether:

- an examination request has been made;
- the application was filed via the PCT;
- a Final Action has been sent;
- a notice of allowance has issued; or
- the Final Fee has been paid.

Subsections 19.03.01 through 19.03.08 describe the procedures and the criteria for acceptance for the different types of amendments that may be made to a patent application.

The amendment must meet the criteria for subject matter and completeness as set forth in sections 19.04, 19.05 and 19.07, to be acceptable to the examiner.

19.03.01 Voluntary amendments before the Request for Examination

Voluntary amendments may be made to a patent application before a request for examination has been submitted. However, the application voluntary amendments filed will not be considered by the examiner at the time of submission. Consideration for acceptance is an examination procedure which is only carried out after an examination request has been made. Voluntary amendments will also be available to public inspection when the application is open to public inspection. Consequently, public disclosure of any new subject matter in a voluntary amendment will occur at the date of opening of the application to public inspection. This could preclude the applicant from filing a new application in respect of that new subject matter at a date later that the one-year anniversary of the date of opening to the public inspection or of the date of the submission of the amendment.

19.03.02 Voluntary amendments after the Request for Examination

The acceptability of voluntary amendments that are filed after a request for examination has been submitted will be considered upon receipt.

When an applicant files a Request for Advanced Examination (Special Order) subsequent to or with an amendment, the cover page to the Request should state, preferably with a clear heading, that a Voluntary Amendment has been recently submitted and indicate the total number of claims to confirm which are to be examined (see section 13.03 for more details regarding Request for Advanced Examination).

19.03.03 Amendments on PCT applications

Amendments made to PCT applications during the international phase under Articles 19 and 34 of the Patent Cooperation Treaty form an integral part of the application at the time of entry into the national phase in Canada. The Canadian national phase application is then subject to the same amendment restrictions as all other Canadian patent applications. Further details on amending PCT applications are given in Chapter22.

19.03.04 Amendments in response to an examiner's requisition

All amendments received in response to an examiner's requisition will be considered with respect to admissibility upon receipt.

19.03.05 Amendments in response to a Final Action

Amendments received in response to a Final Action issued by an examiner are only accepted by the examiner if the amendment(s) or persuasive argument is sufficient to overcome the Examiner's rejection. For amendments in response to Final Actions which are not acceptable to the Patent Office, see section 21.08.

19.03.06 Amendments after Notice of Allowance

Subsection 30(1) of the *Patent Rules* specifies that: where an examiner, after examining an application, has reasonable grounds to believe that the application complies with the *Patent Act* and *Rules*, the Commissioner shall notify the applicant that the application has been found allowable and shall requisition the payment of the applicable Final Fee set out in paragraph 6(a) or (b) of Schedule II within the six-month period after the date of the notice.

Further, subsection 32(1) and (2) of the *Patent Rules* specify that:

(1) except as otherwise provided by the *Patent Act* or *Rules*, after the applicant is sent a notice pursuant to subsection 30(1), no amendment, other than an amendment to correct a clerical error that is obvious on the face of the application, may be made to the application unless the fee set out in item 5 of Schedule II is paid; and

(2) except as otherwise provided by the *Patent Act* or *Rules*, after the applicant is sent a notice pursuant to subsection 30(1), no amendment may be made to the application that would necessitate a further search by the examiner in respect of the application or that would make the application not comply with the *Patent Act* or *Rules*.

An amendment after allowance that broadens the scope of the claims or changes the point of invention (or characterization) so that something additional or different is claimed, will be refused where the change would necessitate further consideration of the art on record or a new search. This applies not only to changes to the claims, but also to additions to or deletions from the description or drawings which have the effect of broadening the scope of the claims or shifting the point of invention (subsection 32(2) of the *Patent Rules*).

Further, subsections 38.2(2) and (3) of the *Patent Act* must be satisfied. Only matter that can reasonably be inferred from the specification as originally filed or shown in the drawings as originally filed may be entered into the specification and drawings.

The examiner rules on the acceptability of each amendment after allowance and, subject to the approval by the Section Head, the amendment is either refused, or accepted and entered into the application file. Procedures for refusal of an amendment after allowance are discussed in section 19.07.04 below.

A fee for considering an amendment after allowance is required (see subsection 32(1) of the *Patent Rules* and paragraph 5 of Schedule II of the *Patent Rules*). However, no fee is required for mere correction of obvious clerical errors and to changes in the title.

Provided an amendment after allowance fee was paid with an original amendment after allowance which was refused, no further fee is required upon resubmission of the same amendment with further argument as to why the amendment should be accepted. If, however, in resubmitting the amendment, significant alterations are made, the new submission is treated as a separate amendment after allowance requiring its own amendment after allowance fee.

19.03.07 Commissioner's withdrawal of Notice of Allowance

In the case where, after a Notice of Allowance has been sent to the applicant but prior to the patent being issued, the Commissioner has reasonable grounds to believe that the application does not comply with the *Patent Act* or *Rules*, the Commissioner will notify the applicant accordingly and returns the application to the examiner for further examination. The Notice will indicate why the application is not allowable. If the Final Fee has been paid, the Commissioner will refund it (subsection 30(7) of the *Patent Rules*). In this circumstance, prosecution of the application will continue and the application may be amended by the applicant.

19.03.08 Amendment after payment of the Final Fee

Generally, applications may not be amended by the applicant after the Final Fee has been paid (section 33 of the *Patent Rules*), although clerical errors may be corrected as provided by section 8 of the *Patent Act*.

19.03.09 Amendments after failure to pay the Final Fee

If an applicant fails to pay the Final Fee within the six-month period after the date of the Notice of allowance, the application will be deemed abandoned (see paragraph 73(1)(f) of the *Patent Act*).

Subsequent to abandonment, the applicant has 12 months within which the application may be reinstated under subsection 73(3) of the *Patent Act*. In order to reinstate the application, the applicant must file a request for reinstatement along with the payment of the reinstatement fee and payment of the Final Fee. Should the applicant wish to amend the application at this stage, the amendment request must be made together with the request for reinstatement. The amendment will be considered with respect to acceptability upon receipt, and the application is subject to examination, pursuant to subsection 73(4) of the *Patent Act*. If the application is found to be allowable, it will advance directly to issuance since the Final Fee has already been paid.

19.03.10 Correction of minor errors

The Patent Office does not generally require correction of minor errors in the specification, such as obvious spelling errors, punctuation and letter inversions. If not corrected, such errors will appear in the printed copy of the patent. However, if the examiner is identifying other defects, minor errors may be pointed out at the same time in the examiner's report. Errors that are in any way deemed to be critical are objectionable, and must be corrected.

19.04 Acceptable Subject Matter

Section 38.2 of the *Patent Act* restricts amendments to the specification or drawings to matter reasonably to be inferred from the specification and the drawings as originally filed[1], no new subject matter may be introduced.

Matter pertaining to prior art with respect to the invention of the application may be added to the specification and the drawings. However, the applicant must acknowledge in the specification that any such matter is prior art, well-known or common general knowledge.

19.04.01 Petitions

Please refer to section 4.01.01 regarding restrictions on amendments to petitions.

19.05 Incomplete and Unsatisfactory Responses

Paragraph 73(1)(a) of the *Patent Act* provides for the abandonment of an application if the applicant does not reply in good faith to any requisition made by an examiner. An amendment that fails to address the defects in the application identified by the examiner, or any other requisition by the examiner, will result in the abandonment of the application (see chapter 20 on abandonment).

The Patent Office may consider that an applicant has failed to reply in good faith to an examiner's requisition if the applicant purposely attempts to mislead or to delay prosecution by:

(a) failing to provide a response to a requisition to correct all the defects identified under subsection 30(2) of the *Patent Rules* by the examiner, or by failing to make satisfactory amendments to avoid those objections;

(b) reintroducing claims to subject matter previously removed to overcome objections made by the examiner; unless the previously removed claims have since become permissible as a result of change of law or practice;

(c) adding informal or other obviously objectionable claims;

(d) failing to provide a response to a requisition for information under section 29 of the *Patent Rules*;

(e) failing to provide a certified copy and proper certification of a previously regularly filed application following a requisition under section 89 of the *Patent Rules*; or

(f) failing to include in the description the date of the original deposit within the International Depositary Authority (IDA) following a requisition under subsection 104.1 of the *Patent Rules*.

Under (a) above, a response does not have to present an amendment to overcome each identified defect but, where it does not, the response should specifically address each identified defect for which an amendment is not presented, indicating why amendment is not necessary.

The procedures for the rejection of an amendment by the examiner are detailed in section 19.07 below.

19.06 Further Examination of Amended Applications

All applications that have been amended are subject to further examination. Any matter introduced by an amendment that is objectionable under the *Patent Act* or the *Patent Rules* will be identified to in an examiner's further requisition. Amended applications may also be subject to a further search of the prior art.

The above does not apply to amendments after the notice of allowance has been sent, since such amendments are refused on receipt if they are found to be unacceptable.

19.07 Unacceptable Amendments

Amendments to applications under examination will not be accepted in the following circumstances:

(a) The amendment introduces new subject matter into the specification or drawings which is not reasonably to be inferred from the specification and drawings as originally filed (subsections 38.2(2) and (3) of the *Patent Act*).

(b) The response to an examiner's requisition is not an attempt in good faith to advance the application to allowance and is therefore contrary to paragraph 73(1)(a) of the *Patent Act*.

(c) After a notice of allowance has issued, if an amendment after allowance fee is required and has not been paid (subsection 32(1) of the *Patent Rules*), or if the amendment adds new matter (subsections 38.2(2) and (3) of the *Patent Act*), necessitates a further search, or if the amendment causes the application in any way to not comply with the *Patent Act* or *Rules* (subsection 32(2) of the *Patent*

Rules).

(d) After the Final Fee has been paid (section 33 of the *Patent Rules*), unless the application has been withdrawn from issue or has been reinstated after abandonment due to non-payment of the Final Fee (subsection 73(4) of the *Patent Act*).

(e) After the expiry of the time for responding to a Final Action except where:

1. the rejection is withdrawn in accordance with subsection 30(5) of the *Patent Rules*;
2. the Commissioner is satisfied after review that the rejection is not justified and the applicant has been so informed;
3. the Commissioner has informed the applicant that the amendment is necessary for compliance with the *Patent Act* and *Rules*; or
4. by order of the Federal Court or the Supreme Court of Canada.

(f) The amendment introduces claims that are not patentable in view of lost conflict matter following a conflict procedure in accordance with section 43 of the *Patent Act*, as it read immediately before October 1, 1989 [2].

19.07.01 Procedure for rejecting new subject matter

When an amendment introduces new subject matter to an application contrary to subsections 38.2(2) and (3) of the *Patent Act*, the examiner will requisition the applicant to remove the new subject matter therefrom, and inform the applicant that the amendment is part of the application file and therefore has or will be open to public inspection with the application.

19.07.02 Procedure for replies not in good faith following a requisition to correct all the defects or to include the date of the International Depository Authority (IDA) in the description

When an examiner considers that a response to an action is not made in good faith following a requisition to correct all the defects under subsection 30(2) of the *Patent Rules,* or to include the date of the International Depository Authority (IDA) in the description under section 104.1 of the *Patent Rules*, the amendment is not accepted. The examiner, at the expiry of the time limit for the response, refers the file and the applicant's response to the Director of Patent Branch. An office letter will remind to the applicant that he or she has the opportunity to present a written argument to explain why the response should be considered a good faith attempt to respond to the examiner's requisition.

- If the argument is not convincing, the application will be deemed abandoned under paragraph 73(1)(*a*) of the *Patent Act* because of the applicant's failure to reply in good faith to the requisition within the required time [3].
- If the argument is convincing, normal prosecution is resumed, and applicant's response is considered by the examiner. The amendment may still not be accepted if new matter is present (section 19.07(a) of MOPOP).

19.07.03 Procedure for replies not in good faith following a requisition to provide a certified copy or information regarding prior art

A response is considered incomplete under the following circumstances::

(a) information requisitioned under subsections 29(1) and (2) of the *Patent Rules* dealing with the provision of prior art or the first publication of a foreign patent is not supplied, and the response is silent in respect to reasons for its absence as required by subsection 29(3) of the *Patent Rules*; or

(b) a certified copy or certification of the actual date of filing of a previously regularly filed application following a requisition under section 89 of the *Patent Rules* has not been provided.

the applicant will be notified by:

- a courtesy communication, requesting the information or reasons why the information is not available before the action due date, if there is still time to respond before the action due date, or

- a notice of abandonment under section 73(1)(a) of the *Patent Act* if the action due date has already passed.

If a response is incomplete because information requisitioned under subsections 29(1) and (2) of the *Patent Rules* dealing with the provision of prior art or the first publication of a foreign patent is not supplied or incomplete, but the explanation for its absence refers to a subsequent or additional submission, the examiner will normally issue another report only to requisition to comply fully with section 29 of the *Patent Rules*. The applicant must then provide the information or state why it is not available as required by subsection 29(3) of the *Patent Rules.*

19.07.04 Procedures for unacceptable amendments after the Notice of Allowance

If the amendment after allowance fee is required but is not submitted with the amendment, the Patent Office will notify the applicant that the required fee must be submitted before the amendment can be considered.

When the examiner decides that an amendment after allowance does not comply (see section 19.03.06 of MOPOP), the applicant will be so advised by the examiner by letter. The letter will indicate to the applicant those parts of the amendment that are objectionable. At this point the applicant may:

- Pay the Final Fee to proceed to issuance with the application in its version before the amendment after allowance, or;

- Resubmit a new amendment after allowance (with a second amendment after allowance fee) absent of the objectionable matter, or;
- Not pay the Final Fee and reinstate the patent application as explained in section 19.03.08 of MOPOP.

19.07.05 Procedure for refusal of amendment after the Final Fee is paid

The Patent Office will notify the applicant that the application is scheduled to issue and cannot be amended.

Endnotes for Chapter 19

1 Re: Application No. 139,723 (Patent No. 1,029,723) [1977] 51 C.P.R. (2d) 95 at 103
Commissioner's Decision No. 145, Application No. 47327 (Patent No. 944,370) [1973]
Commissioner's Decision No. 904, Application No. 315073 (Patent No. 1,149,093) [1981]
Commissioner's Decision No. 938, Application No. 245193 (Patent No. 1,156,966) [1982]

2 Re: Application No. 100,575, [1975] 36 C.P.R. (2d) 283 at 284

3 Commissioner's Decision No. 589, Application 211,920 (Patent No. 1,075,521) [1979]

Chapter 20

Time limits, withdrawal, abandonment and lapse

20.01 Scope of this chapter

This chapter outlines Patent Office policy respecting time limits, extensions of time, withdrawal of applications, abandonment of applications and the lapse of patents. The remedial procedures available to reinstate abandoned applications are also detailed.

20.02 Time limits

The following paragraphs give the time limits prescribed by the *Patent Act* or the *Patent Rules* regarding patent applications and patents.

20.02.01 Withdrawal of an application

A patent application may be withdrawn at any time by written notice from the applicant or the authorized correspondent. An application which is withdrawn more than two months before the expiry of the confidentiality period will not be open to public inspection (subsection 10(5) of the *Patent Act* and section 92 of the *Patent Rules*). Applications withdrawn during the last two months of the confidentiality period will be laid open to public inspection unless there is time to stop the technical preparations to open the application to public inspection (Sections 92 and 146 of the *Patent Rules*).

Applications filed prior to October 1, 1989 may be withdrawn at any time by the applicant or the authorized correspondent and will never be opened to public inspection.

20.02.02 Request for priority

For applications filed after October 1, 1996 a request for priority must be received by the office within four months of the filing date of the application (the subject application). The applicant must provide the Commissioner with the date and country of filing of each previously regularly filed application on which the request for priority is based, before the expiry of the four- month period after the filing date of the subject application and must also provide the Commissioner with the application number of each previously regularly filed application on which the request for priority is based, before the expiry of the later of the four-month period after the filing date of the subject application and the twelve-month period after the date of filing of the previously regularly filed application (section 88 of the *Patent Rules*).

For applications filed in the period beginning on October 1, 1989 and ending the day before October 1, 1996 a request for priority must be received by the office within six months of the filing date of the application(the subject application). The applicant must also provide the Commissioner with the date and country of filing and the application number of each previously regularly filed application on which the request for priority is based before the expiry of the six-month period after the filing date of the subject application (section 142 of the *Patent Rules*).

The time limit for making a request for priority is not extendable in either of the two situations set forth above.

A request for priority may be withdrawn at any time before a patent is issued. If the applicant withdraws a request for priority before the expiry of the confidentiality period it may be possible to delay the laying open of the application to public inspection (subsection 10(4) of the *Patent Act*). The withdrawal must be made within sixteen months of the filing date of the priority application, or a later date if the technical preparations to open the application to public inspection can be stopped (sections 91 and 145 of the *Patent Rules*). The application will be laid open to public inspection at the end of the new confidentiality period (eighteen months from the Canadian filing or eighteen months from the earliest date of the next earliest previously regularly filed application on which a request for priority is based). See chapter 7 on priority for more information.

Applicants of applications filed prior to October 1, 1989 may request priority at any time.

20.02.03 Filing a divisional application

A divisional application must be filed before issue of the original application (parent application) according to Subsection 36(2) of the *Patent Act*. If the parent application becomes abandoned, the divisional application must be filed before the expiration of the time limit for reinstatement of the parent (Subsection 36(3) of the *Patent Act*).

Time limits for filing a divisional application are not extendable.

20.02.04 Completing the application

Non-PCT applications filed on or after October 1, 1996, which do not meet the requirements of subsection 27(2) of the *Patent Act* at the date of filing, are deemed to be incomplete and the office will make every effort to inform the applicant of the reasons for noncompliance by means of a courtesy letter. The letter will specify a time limit prior to which the application can be completed free. The time limit will be a date fifteen months from the filing date, or from the date of the earliest previously regularly filed application on which a request for priority is based, if any. The purpose of not requiring a fee for completing an application during the above period is to encourage applicants to provide the Patent Office with electronically scannable pages for TECHSOURCE and to ensure that all documents listed in (a) to (i) in the previous paragraph arrive at the Patent Office in a timely manner for laying open to public inspection under section 10 of the *Patent Act*.

If at the expiration of a time period of fifteen months from the filing date, or the priority date, if any, the application is still not complete, a Commissioner's Notice will be sent under subsection 94(1) of the *Patent Rules*. The Notice will requisition the applicant to complete the application within a period ending the later of three months after the date of the notice and twelve months after the filing date of the application. Completing the application after the notice has been received will require the payment of the completion fee specified in Item 2 of Schedule II of the *Patent Rules*. Failure to complete the application or to pay the fee within the time period specified in the notice will result in abandonment of the application.

Non-PCT applications filed before October 1, 1996, that are not complete at filing must meet the completion requirements of subsection 148(1) of the *Patent Rules* and pay the completion fee within twelve months of filing in order to avoid abandonment(see chapter 5 for more information on completion requirements).

Completion requirements and time limits for PCT applications depend on whether

Canada was designated or designated and elected on the international application (sections 58 and 62 of the *Patent Rules* and Section 16 of the Canadian Patent Cooperation Treaty Regulations as they read immediately before October 1, 1996). Chapter 22 of this manual details all the requirements and time limits for PCT applications including national phase entry.

The time limits for completing an application are not extendable (subsections 62(3), 94(3),and 148(2) of the *Patent Rules*).

20.02.05 Appointment of a patent agent

Whenever a patent agent must be appointed pursuant to Section 23 of the *Patent Rules*, the Patent Office sends a notice to the applicant. A patent agent must be appointed within three months from the date of the notice. The three-month time limit may be extended under Section 26 of the *Patent Rules*.

20.02.06 Deposits of biological materials

Where the applicant wishes to supplement the description of the invention with a deposit of biological material under Section 38.1 of the *Patent Act*, the deposit must be made with an International Depositary Authority (IDA). For applications filed on or after October 1, 1996, the deposit with an IDA must be made on or before the Canadian filing date. The name of the IDA, the date of the deposit, and the accession number given by the IDA, if not already part of the description at the time of filing, must be provided before the application is open to public inspection under Section 10 of the *Patent Act* (Subsections 104(1) and (2) of the *Patent Rules*). For applications filed before October 1, 1996, the deposit must have been made on or before the filing date of the application either in an IDA or in some other depositary from which samples of the deposit can be obtained by the public. If the deposit was not made with an IDA, the applicant must deposit a sample with an IDA on or before October 1, 1997. Where an application filed before October 1, 1996 (or a patent which may have issued on the basis of such an application) does not already contain the following information, it must be provided on or before January 1, 1998, or before the expiry of the 18 months confidentiality period for the application, whichever is the later: the name of the IDA, the date of the original IDA deposit, the accession number given by the IDA, the name of any non-IDA depositary (if a deposit made before the filing date was not in an IDA) and the date of the deposit in the non-IDA depositary (Section 160 of the *Patent Rules*).

An applicant may file a notice with the Commissioner that a sample of a deposit referred to in an application be furnished only to an independent expert nominated by the Commissioner. This "expert solution" applies until either a patent has issued on the basis of the application or until the application is withdrawn, refused or abandoned and no longer subject to reinstatement. For an application filed on or after October 1, 1996, a notice requesting that access be restricted must be filed before the application is open to public inspection. For an application filed before October 1, 1996, the notice must be filed on or before January 1, 1998, or before the expiry of the confidentiality period for the application, whichever is the later (subsections 104(4) and 160(4) of the *Patent Rules*).

The time limits for deposits are not extendable (subsections 104(5) and 160(5) of the *Patent Rules*).

For full details on deposits of biological materials, see Chapter 17 of this manual.

20.02.07 Request for examination

For applications filed on or after October 1, 1996 an applicant must request examination and pay the prescribed fee pursuant to subsection 35(1) and paragraph 73(1)(d) of the *Patent Act* within five years of filing the application (subsection 96(1) of the *Patent Rules*). The time limit for requesting examination on a divisional application with a filing date (parent's filing date) on or after October 1, 1996 is either five years from the filing date of the parent or six months after the date on which the divisional application was actually filed, whichever date is later (subsection 96(2) of the *Patent Rules*).

For applications filed before October 1, 1996, an applicant must request examination and pay the fee within seven years of filing (subsection 150(1) of the *Patent Rules*). The time limit for requesting examination on a divisional application with a filing date (parent's filing date) before October 1, 1996 is seven years from the filing date of the parent or six months after the date on which the divisional application was actually filed, whichever date is later (subsection 150(2) of the *Patent Rules*).

The time limits for requesting examination set out above are not extendable (subsections 96(3) and 150(3) of the *Patent Rules*).

Where the Commissioner requires the applicant to make a request for examination under subsection 35(2) of the *Patent Act*, a notice will be sent specifying a three month time limit (sections 25, 97 or 151 of the *Patent Rules*). The time limit of that notice may be extended according to section 26 of the *Patent Rules*, but cannot extend beyond the five-year or seven-year time limit for requesting examination under section 96 or 150 of the *Patent Rules*.

20.02.08 Response to a requisition of the Commissioner or an examiner

Where the Commissioner makes a requisition of an applicant pursuant to section 25, section 97 or section 151 of the *Patent Rules* the time limit for a response is three months from the date of the notice. The three-month time limit may be extended under section 26 of the *Patent Rules*.

An examiner's requisition will specify a six month or shorter time limit (paragraph 73(1)(a) of the *Patent Act* and subsection 30(2) of the *Patent Rules*). The six-month time limit cannot be extended. A shorter time limit may be extended under section 26 of the *Patent Rules*, but cannot be extended beyond six months.

20.02.09 Appeals to the Federal Court

An appeal of a Commissioner's Decision to the Federal Court must be taken within three months of the date of mailing of the Commissioner's Decision to the applicant (subsection 18(2) of the *Patent Act*). The time limit for appeal may be extended under section 27 of the *Patent Rules*.

Where an application has been refused by the Commissioner pursuant to section 40 of the *Patent Act*, an appeal to the Federal Court must be initiated within six months of the mailing of the Commissioner's Decision to the applicant (section 41 of the *Patent Act*). This time limit cannot be extended.

20.02.10 Reinstatement of abandoned applications

Applications which have become abandoned under subsections 73(1) or (2) of the

Patent Act may be reinstated within the twelve-month period from the date of abandonment (sections 98 and 152 of the *Patent Rules*). Occasionally applications may become abandoned for more than one reason. Where an application is abandoned for more than one failure to act, the applicant must comply with section 98 or 152 of the *Patent Rules* for each failure to act within twelve months of the date the application was deemed to be abandoned for that failure (sections 98 and 152 of the *Patent Rules*).

The time limit for reinstatement may be extended under section 26 of the *Patent Rules* provided that the request for the extension of time is made before the period for reinstatement expires. If the applicant takes no action prior to the expiry of the twelve-month reinstatement period, the application cannot be reinstated. No retroactive extensions are available.

20.02.11 Final Fee

Where an applicant receives a notice of allowance, the time limit for the payment of the final fee is set out in the notice and shall be six months from the date of the notice (paragraph 73(1)(f) of the *Patent Act* and subsection 30(6) of the *Patent Rules*). The time limit for payment of the final fee is not extendable.

20.02.12 Reissue

A patentee may apply for a reissue of a patent within four years from the issue of the original patent (subsection 47(1) of the *Patent Act*). This time limit is not extendable.

20.02.13 Maintenance Fees

The maintenance fees due and the time limits for their payments for patent applications are given in Item 30, Part VI of Schedule II of the *Patent Rules* (sections 99 and 154 of the *Patent Rules*).

Any or all of the maintenance fees for a particular application or a patent resulting from that application may be paid in advance.

The maintenance fees for divisional applications are due on the same dates as for the parent application. Where maintenance fees are owing at the time of filing a divisional application, all of the fees which would have been due had the divisional application been filed on the filing date of the parent application must be paid at the time of filing of the divisional to avoid immediate abandonment (subsections 99(3) and 154(3) of the *Patent Rules*).

Maintenance fees for patents depend on the filing date of the applications from which they issued. For patents issued on the basis of an application filed after October 1, 1989, the maintenance fees and time limits are set out in Item 31, Part VI of Schedule II of the *Patent Rules* (sections 100, 101, 155 and 156 of the *Patent Rules*). Maintenance fees and time limits for patents issued after October 1, 1989 on the basis of an application filed before October 1, 1989 are given in Item 32, Part VI of Schedule II of the *Patent Rules* (subsections 182(1) and (3) of the *Patent Rules*).

Time limits for payment of maintenance fees are not extendable.

20.03 Time limits expressed in "months"

Applications become abandoned or reinstated if certain actions are taken or not taken within definite time limits usually expressed in a certain number of months. When a requisition is made for an action to be taken within a fixed number of months and the final month has no date the same as the date of the requisition, then the last day of such month is the date the action must be completed. Thus an examiner's requisition with a time limit of six months which is issued on August 29, 30, or 31 must be replied to by February 28 (or February 29 in leap years). Similarly a requisition issued on March 31 setting three months for reply requires a response by June 30.

20.04 Time limits expiring on a dies non

When the last day upon which an applicant or a patentee may act on an application or patent falls on a day when the Patent Office is closed for business the action may be taken on the next day the Patent Office is open (section 78 of the *Patent Act*). If the failure to act sets up new time limits (such as a reinstatement period), the new period starts to run from the extended date, rather than from the original date when the action was due. For example, if a notice of allowance is issued on June 25, 1996 the final fee is due on December 27, 1996 (the Patent Office being closed December 25 and 26). If the final fee is not paid on or before December 27, 1996 the application is deemed to be abandoned on December 27, 1996 and can be reinstated by requesting reinstatement and paying the appropriate fees on or before December 29, 1997 (December 27, 1997 being a Saturday).

The Patent Office is closed for business on all Saturdays and Sundays as well as on the following designated holidays or, if these designated holidays fall on a weekend, the first normal working day following the weekend:

New Year's Day
Good Friday
Easter Monday
Victoria Day
St-Jean Baptiste Day
Canada Day
Labour Day
Thanksgiving
Remembrance Day
Christmas Day
Boxing Day

It should be noted that the Patent Office is not closed on the 1st Monday in August.

20.05 Extensions of time

The time limits discussed in Section 20.02, above, which are indicated as extendable may be extended by the Commissioner (subsection 26(1) and subsection 27(1) of the *Patent Rules*). **The applicant must apply for the extension of time before the expiry of original time limit** and pay the extension fee set out in Item 22, Part IV of Schedule II of the *Patent Rules*. Where the Commissioner is satisfied that the circumstances justify the extension, an extension will be granted, and the applicant notified by letter. The applicant will also receive an office letter if the extension of time is refused. While no affidavit is required, the Commissioner requires reasons why the applicant is unable to complete the required actions within the time period originally set. Unreasonable numbers of extensions or unreasonable lengths of extensions will not be granted by the Commissioner.

20.06 Withdrawal of an application by applicant

An application may be withdrawn at any time. If an application which has never been opened to public inspection is withdrawn more than two months before expiry of the confidentiality period, it will not be opened to public inspection (subsection 10(5) of the *Patent Act* and sections 92 and 146 of the *Patent Rules*). Where an application is withdrawn during the last two months of the confidentiality period, the application will be laid open to public inspection unless there is sufficient time to stop the technical preparations to open the application to public inspection. A request for withdrawal must be in writing. Any fee which has been paid prior to the date of withdrawal is not refundable except under subsections 4(3) and (4) of the *Patent Rules*. An application which is withdrawn after being opened to public inspection, will remain in the search files of the Patent Office.

20.07 Abandonment

An application is deemed to be abandoned under section 73 of the *Patent Act* if the applicant does not

(a) reply in good faith to any requisition of an examiner within the time limit specified;

(b) complete the application and pay the completion fee within the time limit specified;

(c) pay the prescribed maintenance fees within the time limit specified;

(d) make a request for examination and pay the prescribed fee within the time limit specified;

(e) make a request for examination and pay the prescribed fee, when required to do so by the Commissioner, within the time limit specified;

(f) pay the final fee within the time limit specified; or

(g) comply with any requisition of the Commissioner within the time limit specified (section 25 of the *Patent Rules*).

The time limits (or extended time limits) specified for the above actions are given in Section 20.02 of this manual.

An application may become abandoned for more than one failure to act as above (e.g. an application may become abandoned for failure to respond to an examiner's requisition and also be deemed abandoned for failure to pay a maintenance fee at a later date during the abandoned period for failure to respond to the examiner's requisition).

A notice of abandonment will normally be sent by the Office when an application is deemed abandoned. However, although a notice of abandonment (notice that the patent is about to lapse) has been sent in a particular case, it should not be assumed that notice will be sent in every case. Such notices are sent as a courtesy only and the Patent Office takes no responsibility for failure to send a notice in a particular situation. If an application is abandoned for more than one failure to act, additional notices will be sent for each failure during the time period within which the applicant can reinstate the application.

20.08 Reinstatement

Where an application becomes abandoned under subsection 73(1) or (2) of the *Patent Act*, the applicant may reinstate the application according to section 73(3) of the *Patent Act* and section 98 or 152 of the *Patent Rules* within twelve months of the date the application was deemed abandoned by;

i) making a request for reinstatement,
ii) taking the action that should have been taken in order to avoid the

abandonment, and

iii) paying the fee set out in Item 7, Part I of Schedule II of the *Patent Rules*.

Where an application is abandoned for more than one failure to act, the applicant must take the above actions for each failure to act within twelve months of each failure (sections 98 and 152 of the *Patent Rules*).

For example, an application may become abandoned on two grounds if applicant fails to respond to an examiner's requisition within the six month time limit and also fails to pay a maintenance fee that falls due during the time when the application was abandoned; for that the application to be reinstated, the applicant must request reinstatement, respond to the examiner's requisition, submit the maintenance fee and submit two reinstatement fees within twelve months of the abandonment for failing to respond to the examiner's requisition. If the applicant attempts to reinstate without paying the maintenance fee and the second reinstatement fee, the application will remain abandoned (for failure to pay the maintenance fee) but the time limit for reinstatement will be extended to the end of the twelve-month period from the date the maintenance fee was due. If the period for reinstatement has expired before payment of the reinstatement fee or before a request for an extension of the reinstatement period is made, the application can never be reinstated.

20.09 Lapsed patent

A lapsed patent is one which no longer confers any patent rights to the patentee because the appropriate maintenance fees have not been paid.

Maintenance fees for patents issued on the basis of applications filed after October 1, 1989 are payable for each one-year period between the second and twentieth anniversaries of the date of filing of the application in Canada (sections 100, 101, 155, and 156 of the *Patent Rules* and Item 31, Part VI of Schedule II of the *Patent Rules*).

Maintenance fees are due before the first day of each of the one-year periods they cover. For example, payment is due on or before the eleventh anniversary for the one-year period ending on the twelfth anniversary.

Any or all of the maintenance fees for a particular application or a patent resulting from that application may be paid in advance.

Late payment of the maintenance fees for patents are also accepted by the office if the payment is made within the one-year period the fee covers and the prescribed late payment fee is also paid. For example, the maintenance fee for the one-year period ending on the seventeenth anniversary of the filing date can be made, with the additional fee for late payment, on or before the seventeenth anniversary date. The time limits for payment of maintenance fees for patents cannot be extended (sections 102 and 157 of the *Patent Rules*).

Maintenance fees for patents issued on or after October 1, 1989 on the basis of an application filed before October 1, 1989 are payable for each one-year period between the second and the seventeenth anniversaries of the date on which the patent was issued. Section 182 of the *Patent Rules* and Item 32, Part VI of Schedule II of the *Patent Rules* specify the maintenance fees payable and the dates on which the payments are due. Payments are due before the first day of the one-year period the fee covers, or on or before the last day of the one-year period the fee covers if the late payment fee is also paid.

Any or all of the maintenance fees for a particular application or a patent resulting from that application may be paid in advance.

The time limits specified in Part VI of Schedule II of the *Patent Rules* cannot be extended (section 182(7) of the *Patent Rules*).

A patent is deemed to have lapsed at the expiration of the time specified in Schedule II of the *Patent Rules* (subsection 46(2) of the *Patent Act*). **A lapsed patent cannot be revived.**

Notification of lapsed patents will be published in the Canadian Patent Office Record.

20.10 Jurisprudence

The following decisions of the courts are of importance in considering the subject matter of this chapter:

lapse		
Zeneca v Canada	66 CPR (3d) 169	1996

Chapter 21
Final Actions and Post-Rejection Practice

21.01 Scope of this chapter

This chapter addresses examination practice surrounding the rejection of an application by an examiner, the writing of a *Final Action* to inform the applicant of the rejection, and the review of a rejected application by the Patent Appeal Board and the Commissioner of Patents.

Where an examiner, after having previously identified one or more defects in an application and having requisitioned the applicant to amend the application in order to comply with the *Patent Act* and *Patent Rules* or to provide arguments as to why it does comply, has considered the applicant's response and has reasonable grounds to believe that the application still does not comply with the *Patent Act* or *Patent Rules* and that the applicant will not amend the application to comply, the application may be rejected.

A *Final Action* is the examiner's report that notifies the applicant that their application has been rejected and that sets forth the examiner's reasons for the rejection. In essence, rejecting an application and writing a *Final Action* is a mechanism that resolves impasses between an examiner and an applicant.

This chapter provides guidance on determining when a *Final Action* is warranted, the content of the *Final Action* itself, and the various post-rejection practices that lead to disposal of the application by allowance or refusal. A significant portion of the chapter details the practices of the Patent Appeal Board during the review of a rejected application by the Commissioner of Patents.

21.02 Overview

As is discussed in Chapter 13 of this manual, the examination of a patent application involves its consideration by a patent examiner.

Where, after examining the application, the examiner has reasonable grounds to believe that it complies with the *Patent Act* and *Patent Rules*, the examiner will approve the application for allowance [see section 13.10 of this manual].

Where, instead, the examiner considers that the application does not comply with the *Patent Act* or *Patent Rules*, the examiner will, in accordance with subsection 30(2) of the *Patent Rules*, inform the applicant of the application's defects and requisition the applicant to amend the application to comply or to provide arguments as to why it does [see section 13.05 of this manual].

Examination typically proceeds through an exchange of examiner's reports and responses from the applicant. The aim of this process is to reach a conclusion as to the allowability of the application.

In some cases, the examiner and applicant will reach an impasse as to whether an identified defect truly is a defect. Where this occurs, the examiner will reject the application and notify the applicant in a *Final Action*.

Subsection 30(3) of the *Patent Rules* provides that:

> *Where an applicant has replied in good faith to a requisition referred to in subsection (2) within the time provided but the examiner has reasonable grounds to believe that the application still does not comply with the Act or these Rules in respect of one or more of the defects referred to in the requisition and that the applicant will not amend the application to comply with the Act and these Rules, the examiner may reject the application.*

As will be seen later in the chapter, an applicant's ability to amend the application after it has been rejected may be limited. Consequently, although an application can, in principle, be rejected as soon as an impasse occurs with respect to a single defect, in practice a rejection will usually not occur if the examiner considers that continued correspondence with the applicant is serving to resolve other substantive defects.

Broadly speaking, it is desirable for a *Final Action* to be written when all defects have been resolved other than those on which an impasse exists. In practice, where this would unduly prolong prosecution, a *Final Action* can be written even though an impasse has not been reached with respect to some defects. Furthermore, where an impasse has been reached on all the substantive issues previously identified as defects, but new defects (substantive or otherwise) were introduced by the applicant, these new defects can be identified in a *Final Action*.

The decision as to when it is appropriate to reject an application must be made considering the overall context of examination, including the length of prior prosecution, the nature of the outstanding defects remaining, the extent to which these had been discussed by the examiner and the applicant, and whether the examiner considers it likely that further prosecution would advance the application to allowance.

Subsequent to a rejection, the examiner will review any responses to the *Final Action* that were made by the applicant before the expiry of the time to respond. Where the examiner does not withdraw the rejection, the Patent Appeal Board and the

Commissioner of Patents will review the rejected application, possibly in light of further submissions by the applicant. Following the review, the Commissioner may allow or refuse the application, or indicate a period of time during which the application may be amended in a manner specified by the Commissioner, such that it would be allowable if so amended but will otherwise be refused.

When an application has been refused by the Commissioner, the applicant may appeal the Commissioner's decision to the Federal Court.

21.03 Examination before a rejection

At each stage of examination, an examiner will endeavour to identify all the defects in the application and inform the applicant of these in a report in accordance with subsection 30(2) of the *Patent Rules* [see sections 13.05 and 13.06 of this manual].

Early in prosecution, it is possible that certain defects are interrelated, complicating their identification and resolution. Ambiguity in a claim, for example, could make it difficult to conclusively determine whether the claimed matter is novel or unobvious. As prosecution advances, the applicant's amendments and arguments in response to a requisition may serve to change the examiner's understanding of the invention. It is, thus, understandable that different or additional defects may be identified in subsequent reports.

It is also possible that an examiner may miss a defect during the analysis of the application; nevertheless it is required that the examiner identify these defects once aware of them.

As prosecution advances, it may become apparent that the examiner and applicant do not agree as to whether certain defects are present. Typically, where an applicant responds to a requisition by providing arguments as to why the application does comply but the examiner still considers that the application is defective, a further report identifying this same defect will provide a greater level of detail regarding the examiner's analysis. As appropriate, the applicant's arguments will be addressed in the examiner's subsequent report.

Where it appears that prosecution is approaching an impasse, an examiner will usually advise the applicant of this fact by indicating in the report being written that a further report on substantially the same points may be made final. Although it is not a requirement of the *Patent Act* or *Patent Rules* that such a warning be provided, it should be done whenever doing so would be reasonable in the circumstances.[1]

The last report written before a *Final Action* (informally referred to as a "pre-final" action) should provide completely elaborated arguments supporting the examiner's conclusion that the application is defective. Recognising that the applicant's opportunities to amend the application subsequent to the expiry of the time to respond to a *Final Action* may be limited under subsection 30(6) of the *Patent Rules*, it is very important to ensure that all defects have been identified in a "pre-final" action. The limitations on amending the application post-rejection provide the reason for advising the applicant that the examiner is considering making the next report a *Final Action*: knowing their application faces imminent rejection, the applicant may consequently wish to take special care in responding to the pre-final action.

21.04 Rejecting an application

An examiner may reject an application where the requirements of subsection 30(3) of the *Patent Rules* are met, namely

1) an examiner has previously identified a defect in an application, and requisitioned the applicant to amend the application in order to comply with the Act and Rules or to provide arguments as to why it does comply;
2) the applicant has responded to the requisition, but the examiner considers that the application still does not comply with the Act or Rules in respect of one or more of the defects referred to in the requisition; and
3) the examiner believes that the applicant will not amend the application to comply with the Act and Rules.

Having rejected the application, the examiner then notifies the applicant of the reasons for having rejected the application under the provisions of subsection 30(4) of the *Patent Rules*, namely

> *Where an examiner rejects an application, the notice shall bear the notation "Final Action" or "Décision finale", shall indicate the outstanding defects and shall requisition the applicant to amend the application in order to comply with the Act and these Rules or to provide arguments as to why the application does comply, within the six-month period after the requisition is made or, except in respect of Part V, within any shorter period established by the Commissioner in accordance with paragraph 73(1)(a) of the Act.*

Considering the guidance in section 21.03, it can be understood that the analysis of the defects identified in a *Final Action* is to be comprehensive in nature. Identifying a defect for the first time in a *Final Action*, while occasionally necessary, is generally not desirable. In particular, if a major defect (anticipation, obviousness, lack of utility, non-statutory subject matter, insufficiency, etc.) was overlooked in prior prosecution, a further regular requisition identifying the defect is most likely necessary in order to allow the applicant an opportunity to have their response be evaluated prior to any rejection.

If a new, significant defect was introduced with amendments made in response to the previous report, the examiner will have to exercise judgement as to whether or not a *Final Action* is appropriate.[2]

While reasonable efforts must be made to avoid identifying a defect for the first time in a *Final Action*, it is also necessary to consider the effect of unduly prolonging prosecution. Where a new defect is introduced by the applicant late in prosecution, it may not be appropriate to delay rejection simply to deal with it. Furthermore, where a newly identified defect is readily understandable and easily fixed (e.g. a missing antecedent, incorrect claim numbering, etc.), it may not be necessary to delay rejection.

What should not be done, however, is to ignore an identified defect in order to simplify the *Final Action*. The examiner must decide whether a newly identified defect requires a further report under subsection 30(2) of the *Patent Rules* or if it can be included in a *Final Action*.

21.04.01 The *Final Action* Report

A *Final Action* is a particular type of examiner's report, and will usually not follow the regular style and form of a report written under subsection 30(2) of the *Patent Rules*.

The opening paragraph of a *Final Action* will identify that it contains a requisition under subsection 30(4) of the *Patent Rules*, and will feature the words FINAL ACTION prominently. The report will also include an indication that the application is being rejected pursuant to subsection 30(3) of the *Patent Rules*.

The preamble of the report should identify, in broad terms, the defects that have led to the rejection and which claims are considered defective and which are allowable.

The entire report should be drafted bearing in mind the point of dispute. Where the examiner and the applicant agree on certain facts or conclusions pertaining to the disputed defect, this should be noted (with reference to any relevant correspondence) but it is not necessary to comprehensively revisit these aspects.[3]

The goal of the *Final Action* is to make the point of disagreement clear, to set out the applicant's position as understood by the examiner, and the examiner's reasoning for considering the application to still not comply with the Act or Rules. The *Final Action* should be drafted so that interested persons reading it (including the applicant, Patent Appeal Board, the Commissioner or the Court) can readily understand the point of the dispute and the examiner's reasons for concluding that the application does not comply with the Act or Rules despite any arguments to the contrary from the applicant.

Although the actual layout and presentation of a *Final Action* can be tailored to fit the facts of the case under consideration, the following information should be provided where relevant.

1) A summary of the application, setting forth the invention as claimed with an emphasis on the relevant claims. The summary should clearly identify any aspects of the claims that are central to the impasse.

2) An identification of any allowable claims.

3) An identification of any relevant prior art and a discussion of the pertinent teachings of those disclosures.

4) A summary of the relevant prior prosecution, setting forth in broad terms how the discussion of the alleged defect has proceeded. This section may also provide a summary of the applicant's reasons for believing the application is not defective.

5) A discussion of the legal, jurisprudential and administrative considerations relevant to the impasse, particularly where these are central to the dispute.

6) The grounds for rejection, which should provide a comprehensive analysis of the defects that led to the rejection, including a rebuttal where appropriate of the applicant's arguments.

7) A summation, wherein the grounds for rejection are very briefly recapitulated.

It may be beneficial to divide the report into sections, using clear headings to identify what is being discussed in each section.

To the extent practical, the *Final Action* should be written so that it can be understood independently of other reports or responses. More particularly, pertinent arguments should not be incorporated by reference to other documents but should, minimally, be summarised in the *Final Action* itself.

21.05 Responses to a *Final Action*

An applicant may respond to a *Final Action* by submitting amendments to make the application compliant with the *Patent Act* and *Patent Rules* or by submitting arguments as to why the application does comply.

Upon receipt of a response to the *Final Action* before the expiry of the time to respond, the examiner will review the application.

21.05.01 Responses that overcome the rejection

If, after considering any amendments and arguments submitted by the applicant, the examiner considers that the application complies with the Act and Rules, it will be allowed pursuant to subsection 30(5) of the *Patent Rules*, which provides that

> *If before the expiry of the period under subsection (4), the applicant amends the application or provides arguments and the examiner has reasonable grounds to believe that the application complies with the Act and these Rules,*
>
> > *(a) the examiner shall notify the applicant that the rejection is withdrawn; and*
> >
> > *(b) the Commissioner shall notify the applicant that the application has been found allowable and requisition the payment of the applicable final fee set out in paragraph 6(a) or (b) of Schedule II within the six-month period after the date of the notice of allowance.*

The notification under paragraph 30(5)(*a*) of the *Patent Rules* takes the form of an Office letter sent to the applicant by the examiner. It is a separate piece of correspondence from the notice of allowance.

21.05.02 Responses that do not overcome the rejection

If, after considering any amendments and arguments submitted by the applicant, the examiner considers that the application still does not comply with the Act or Rules, the examiner's next steps depend on whether the time to respond to the requisition has expired or not.

If the time to respond has not expired, the examiner may contact the applicant to inform them of the examiner's conclusions and to determine whether the applicant wishes to submit further amendments and/or arguments prior to the expiry of the time to respond to the requisition. This would be particularly appropriate in instances where the applicant has partially addressed the grounds for rejection and where it appears a further response could make the application allowable.

If the time to respond to the requisition has expired, the provisions of subsection 30(6) of the *Patent Rules* apply. Thus,

> *If the applicant amends the application or provides arguments within the time referred to in subsection (4) but, after the expiration of that time, the examiner does not have reasonable grounds to believe that the application complies with the Act and these Rules,*

> *(a) the Commissioner shall notify the applicant that the rejection has not been withdrawn;*
>
> *(b) any amendments made within the time referred to in subsection (4) shall be considered not to have been made; and*
>
> *(c) the rejected application shall be reviewed by the Commissioner.*

By virtue of paragraph 30(6)(*b*) of the *Patent Rules*, any amendments made after the *Final Action* was sent are considered not to have been made unless the examiner determines that they place the application in condition for allowance. If, after the time for responding to the *Final Action* has expired, an examiner concludes that the application is still not allowable, the examiner will prepare the case for review by the Commissioner.

21.06 The *Summary of Reasons*

A *Summary of Reasons* is a document written by an examiner in preparation for the Commissioner's review of a rejected application pursuant to paragraph 30(6)(*c*) of the *Patent Rules*. It is written only when the time to respond to the *Final Action* requisition has expired and the applicant's response has not overcome the reasons for rejection [see 21.05.02].

In the *Summary of Reasons*, the examiner briefly sets out why they still do not have reasonable grounds to believe that the application complies with the *Patent Act* and *Patent Rules*. Since the rejection is being maintained, any amendments proposed by the applicant subsequent to the rejection are considered not to have been made. Consequently, the examiner's reasons for considering the application not to comply with the Act and Rules will primarily be those set out in the *Final Action* itself. Reasons given in the *Final Action* should not be comprehensively repeated in the *Summary of Reasons*, which (as its name implies) is intended to be a brief document.

The *Summary of Reasons* should identify and address any new considerations arising from the applicant's post-rejection correspondence received up to the expiry of the time to respond to the requisition, such as new arguments in support of patentability, relevant jurisprudence or changes to Office practice.

If the applicant has proposed amendments, the examiner should provide a concise analysis of the effect of these amendments. The *Summary of Reasons* will provide information such as whether proposed amendments would have overcome, or addressed in part, certain of the examiner's grounds for considering the application defective or would have changed the examiner's reasons for considering the claims defective. It would be particularly noted if the proposed amendments would have rendered certain claims allowable. Similarly, any defects present in the proposed amendments would be identified.

It should also be indicated if certain of the applicant's arguments were compelling, even if the arguments themselves were insufficient to give the examiner reasonable grounds to consider the application to comply with the Act and Rules. This might be the case, for example, where an applicant explains how the invention may be distinguished from cited prior art, but the arguments are based on features not defined in the claims.

In view of the above, it can be understood that the *Summary of Reasons* is intended to assist in the review of the application by providing a concise, high-level overview of important considerations arising from any post-rejection correspondence with the applicant as well as any information relevant to the review which was not available at the time the application was rejected.

21.07 Review of a rejected application

A review of a rejected application is, as previously noted, required by subsection 30(6) of the *Patent Rules* whenever the applicant's response to a *Final Action* does not place the application in condition for allowance.

While the review is primarily focussed on resolving the impasse that led to a rejection, the review is also comprehensive, meaning that any apparent defects in the application, even beyond those indicated in the *Final Action* and/or the *Summary of Reasons*, will be identified at this stage.[4] This point is highlighted in paragraph 30(6)(*c*) of the *Patent Rules* which states that the "rejected application" is reviewed.

It can be broadly stated that the intention of the review process is to achieve efficiency, finality, and compliance of the application with the *Patent Act* and *Patent Rules* while adhering to the principles of natural justice and procedural fairness.

The review of an application can be terminated by withdrawing the application, and will typically not proceed during periods where the application is deemed abandoned by operation of law. The review is also terminated where an application remains abandoned outside the reinstatement period.

21.07.01 Referral to the Patent Appeal Board

The Commissioner is assisted in performing the review of a rejected application by the Patent Appeal Board (PAB).[5] The PAB is an advisory body consisting of a Chair and several members, each of whom is a senior official of the Patent Office with previous experience as a patent examiner. The review of a specific application is typically performed on behalf of the Commissioner by a panel of three members of the PAB. In order that the review of the application be impartial, these members must not have participated in the prosecution of the application or have previously given advice in respect thereto.

The review occurs only after the time limit for responding to the *Final Action* has expired and the *Summary of Reasons* has been prepared and forwarded to the PAB. At this point, control over the application is transferred to the PAB.

It is to be noted that the review process is an *ex parte* process, meaning that there is only one party to the proceedings, namely the patent applicant. The process is a continuation of the administrative procedures of the office with regard to patent applications under the *Patent Act*, but is performed at arm's length to the examination divisions.

21.07.02 Communication with the applicant

During the review process, an applicant can expect to be contacted by the Board several times. These communications may cover both administrative and substantive matters relating to the review.

Administrative matters include informing the applicant that the application has been transferred to the PAB and details relating to giving the applicant an opportunity to be heard.

Substantive matters include keeping the applicant informed of any matters affecting the review, including providing the applicant with a copy of the *Summary of Reasons*.

When a rejected application is transferred to the PAB, the applicant is informed in an initial letter from the Board. This initial letter will, minimally, notify the applicant, as required by paragraph 30(6)(*a*) of the *Patent Rules*, that the examiner's rejection has not been withdrawn [see 21.05.02] and that the case has been transferred to the PAB. A copy of the *Summary of Reasons* [see 21.06] will accompany the letter.

Where the applicant responded to the *Final Action* by submitting amendments, the initial letter will also confirm, per paragraph 30(6)(*b*) of the *Patent Rules*, that because the rejection was not withdrawn, any amendments received in response to the *Final Action* within the time referred to in subsection 30(4) are considered not to have been made.

Additional information relating to the review, including the offer of an opportunity to be heard, may be included in the initial letter or dealt with separately.

Communications from the PAB generally include a time period to respond. It is important to note, however, that a letter from the PAB is not a requisition. If it is not responded to within the time period stated, the application will not be deemed abandoned. Consequently, failure to respond to a PAB communication will not suspend the review process.

21.07.03 Issues arising during the review process

During the review, the panel may come to believe that defects beyond those identified in the *Final Action* are present in the application. The identification of such defects may result, for example, from the panel interpreting the application differently from the examiner, or be in view of different interpretations of jurisprudence or office practices, or be in view of new art submitted through a late-filed protest, art cited in recent foreign prosecution or a change in the *Patent Act* or *Patent Rules*.

Where a new defect is identified during the review, the applicant is given notice of the issue and an opportunity to respond, which includes the possibility of proposing amendments to address the defect. Amendments proposed by the applicant, if they correct the defect, may be later required to be made by the Commissioner in a Commissioner's Decision under paragraph 31(*b*) of the *Patent Rules* [see 21.08.03]. The opportunity to respond is demanded both by the requirements of natural justice and by subsection 30(6.1) of the *Patent Rules*, which provides that:

> *If, during the review of a rejected application, the Commissioner has reasonable grounds to believe that the application does not comply with the Act or these Rules in respect of defects other than those indicated in the Final Action notice, the Commissioner shall inform the applicant of those defects and invite the applicant to submit arguments as to why the application does comply within the time specified by the Commissioner.*

Where a potential defect is identified during the review process, the panel may raise the matter directly with the applicant or may request that the examiner provide an analysis in relation thereto. In exceptional cases, the panel may also determine that a further search and analysis of the prior art is necessary in relation to the defect.

Where an analysis is requested of an examiner, the examiner's findings are presented in a *Supplemental Analysis*, a document similar in form to a *Summary of Reasons* but addressing only the issue identified by the panel.

Where a *Supplemental Analysis* is requested of an examiner, the applicant will be duly informed and will receive a copy of the analysis.

A response to a *Supplemental Analysis*, including proposed amendments, should only address the defect under consideration in the analysis.

21.07.03*a* Clarification of certain matters

It is desirable that the review proceed, as far as is reasonably practical, on the basis of a common understanding of the matters at issue. Therefore, in addition to the identification of new defects, it is also possible that the panel may wish to clarify certain other matters with the applicant during the review process.

Such clarifications are intended to ensure that the applicant and the panel have the same understanding of, for example, the examiner's grounds for rejection, the applicant's arguments, the applicable Office practice, or of certain relevant facts.

Where it appears to the panel that clarification is desirable, a memo will be sent to the applicant setting out the matters that, in the panel's view, may require clarification. Where the examiner's input is necessary, it may be provided in the form of a *Supplemental Analysis*.

The applicant will be given a period of time to respond, and may respond with written submissions or with oral arguments at the hearing.

21.07.04 Opportunity to be heard

Subsection 30(6.4) of the *Patent Rules* specifies that the applicant must be given an opportunity to be heard before any refusal. The applicant will therefore generally be invited to participate in a hearing. The PAB will make reasonable efforts to accommodate the applicant's schedule, but if the applicant is unable to participate in a timely hearing the review will proceed nonetheless.

The applicant is not required to attend a hearing, and may instead request that the review proceed on the basis of the written record.

Prior to any hearing, the panel will perform an initial review of the case both to ensure that the outstanding issues have been clearly identified and articulated and that there are no other issues requiring clarification, such as defects identified pursuant to subsection 30(6.1) of the *Patent Rules* [see 21.07.03].

The purpose of the hearing is to provide the applicant with a further opportunity to develop and explain the reasons for contending that the application is not defective (on the basis of the grounds raised either by the examiner or by the PAB during the review process) or that proposed amendments overcome the identified defects. Written arguments and/or additional evidence should be presented to the panel well ahead of the hearing, to ensure the panel has sufficient time to consider them. When any new legal or technical argument or fresh evidence relevant to the grounds raised by the examiner comes to the applicant's attention it should be presented as early as possible and not deferred until the review stage (i.e., the applicant's best case should be made during prosecution before the examiner and not only before the PAB).

The hearing may occur in person, via teleconference or via videoconference, at the option of the applicant, and may include the assigned panel, the applicant and applicant's representative, as well as the examiner and the examiner's supervisor.

The hearing is primarily an opportunity for the applicant to present its position in order to advance prosecution, with input from the panel.

Typically a hearing begins with an oral presentation by the applicant. The panel may pose questions to the applicant during or after the applicant's presentation of arguments, depending both on the need to intervene and the applicant's preferences. The examiner and examiner's supervisor are normally present and may be called upon by the panel to answer questions in relation to the defect(s) and any technical matters. The applicant is given an opportunity to make any final comments before the conclusion of the hearing. No cross-questioning between the applicant and examiner is permitted.

Points of fact agreed to during the hearing, or concessions made by the applicant, will be taken into account in the recommendation to the Commissioner. Although it is expected that the applicant will be prepared to address any questions posed at the hearing, it may be acceptable, should an unexpected issue arise during discussion, for the applicant to make additional submissions to the panel within a reasonable period thereafter.

Since the panel must make a recommendation to the Commissioner, no decision regarding disposal of the application may be made at the hearing.

21.07.05 Decisions without a hearing

It is not necessary in every case to hold a hearing. As noted in 21.07.04, the applicant may decline the invitation for a hearing. Where this is done, the assigned panel will review the case and provide a recommendation to the Commissioner taking into account the written record before it, including any further written submissions the applicant has provided.

It is also possible that the panel, after its initial review of the case, may conclude that the application complies with the Act and Rules. Where the Commissioner agrees with this conclusion, there is no need to invite the applicant to attend a hearing. Subsection 30(6.4) of the *Patent Rules* does not require a hearing where the application will be allowed.

21.07.06 Recommendation to the Commissioner

At the conclusion of the panel's review, the panel will deliberate and formulate a recommendation to the Commissioner. The panel considers the facts and law related to the particular matter before them, including any arguments and evidence adduced by the applicant during the review.

The recommendation is provided as written reasons that generally include an explanation of the invention being considered, background information on the prosecution, an identification of the issues to be decided, relevant statutory authority, pertinent jurisprudence, a summary of the positions of the examiner and applicant, a detailed analysis of the issue(s) including factual findings, and a final recommendation of the panel.

The Commissioner of Patents is then briefed on the case and reviews the recommendation prior to rendering a final decision.

21.08 The Commissioner's Decision

The Commissioner's Decision provides reasons for arriving at the decision and explains any findings with reference to the *Patent Act*, *Patent Rules* and pertinent jurisprudence. Typically, the Commissioner adopts the panel's reasons.

In addition to its importance to the applicant, a Commissioner's Decision can also provide insight and/or guidance to applicants and patent examiners as to the current understanding of the state of the law and Office practice. Commissioner's Decisions are carefully reviewed when practice guidance is provided to examiners.

A copy of the decision is sent to the applicant (by registered mail if the application is refused, as per section 40 of the *Patent Act*). These decisions become part of the prosecution file and are therefore open to public inspection, except for decisions made in respect of applications filed prior to October 1, 1989 which are only published with the permission of the applicant.

A database of published Commissioner's Decisions is maintained by the Office and may be accessed via the CIPO web site.

In the following sections, the possible outcomes of Commissioner's Decisions are set out, along with the effect of each.

21.08.01 Rejection not justified and application allowable

Subsection 30(6.2) of the *Patent Rules* provides that

> *If, after review of a rejected application, the Commissioner determines that the rejection is not justified on the basis of the defects indicated in the Final Action notice and has reasonable grounds to believe that the application complies with the Act and these Rules, the Commissioner shall notify the applicant that the rejection is withdrawn and that the application has been found allowable and shall requisition the payment of the applicable final fee set out in paragraph 6(a) or (b) of Schedule II within the six-month period after the date of the notice of allowance.*

In such a case the applicant will be notified in the Commissioner's Decision that the rejection is withdrawn and that the application will be allowed.

Once the application has been allowed, it is treated in the same manner as any other allowed application [see section 13.10 of this manual], with a Notice of Allowance being sent to the applicant requisitioning payment of the final fee.

21.08.02 Application refused

If upon review of the rejected application the Commissioner is of the view that the examiner's rejection is justified, or that the application does not comply with the Act or Rules on the basis of defects identified during the review process, and it is not evident that the application can be made compliant through a directed amendment per paragraph 31(*b*) of the *Patent Rules*, the Commissioner will refuse the application pursuant to section 40 of the *Patent Act*. The refusal will be indicated in the Commissioner's Decision which will also specify the applicable six month period in which to initiate an appeal to the Federal Court.

21.08.03 Amendments required by the Commissioner

As per subsection 30(6.3) of the *Patent Rules*

> *If, after review of a rejected application, the Commissioner determines that the application does not comply with the Act or these Rules, but that specific amendments are necessary, the Commissioner shall notify the applicant that the specific amendments have to be made within three months after the date of the notice. If the applicant complies with that notice, the Commissioner shall notify the applicant that the application has been found allowable and shall requisition the payment of the applicable final fee set out in paragraph 6(a) or (b) of Schedule II within the six-month period after the date of the notice of allowance.*

The applicant will be notified of the necessary amendments in the Commissioner's Decision pursuant to paragraph 31(*b*) of the *Patent Rules*. The amendments required in a Commissioner's Decision may be based on proposed amendments submitted during the review process, both as a result of the applicant's own initiative or as a result of defects identified during the review process. They may also be based on the Commissioner's findings alone as to how the application can be made compliant with the Act and Rules.

If in response to the requirement for amendment the applicant does not make the necessary amendments, or makes amendments beyond those required, the Commissioner will refuse the application in accordance with section 40 of the *Patent Act.*[6]

21.09 Appeals of Commissioner's Decisions

Where the Commissioner refuses a patent application under section 40 of the *Patent Act*, section 41 of the Act states that

> *Every person who has failed to obtain a patent by reason of a refusal of the Commissioner to grant it may, at any time within six months after notice as provided for in section 40 has been mailed, appeal from the decision of the Commissioner to the Federal Court and that Court has exclusive jurisdiction to hear and determine the appeal.*

The decision of the Federal Court may be appealed to the Federal Court of Appeal and, with leave, to the Supreme Court of Canada.

21.10 Prosecution following a decision of the Court

Following a decision of the Court, the Commissioner takes action in accordance with any resulting orders of the Court. Of note is that the Court has the authority to order the entering of amendments, per paragraph 31(*d*) of the *Patent Rules*

> *An application that has been rejected by an examiner in accordance with subsection 30(3) shall not be amended after the expiry of the time under subsection 30(4) for responding to the examiner's requisition except*
>
> > *(d) by order of the Federal Court, the Federal Court of Appeal or the Supreme Court of Canada.*

Endnotes for chapter 21

1. A further report would not be written, for example, solely to advise the applicant that the next report may be made final, where the report otherwise simply reiterates the arguments presented in the previous report.

2. A further report may not be necessary, for example, where the examiner has previously identified a defect as a non-compliance with one section of the Act or Rules, but later realises that for the same or substantially the same reasons the defect in question results in non-compliance with a further section of the Act or Rules or that the defect should have been identified as non-compliance with a different section of the Act and Rules than that previously identified.

3. If the examiner had previously identified something as belonging to the common general knowledge, and the applicant had acknowledged this in correspondence, it would not be necessary to further substantiate that it is, in fact, common general knowledge. Similarly, if a claim with five elements was identified as being anticipated in view of a document D1, and the applicant agrees that D1 teaches four of the five claimed elements, it is not necessary to elaborate on those features in the reasons for the rejection; the point of disagreement is whether D1 discloses the fifth element.

4. Despite the fact that any apparent defects will be identified, a review begins with the presumption that the search and examination prior to the review stage is complete and comprehensive.

5. The PAB was created in a *"Notice to the Patent Profession" (re: creation of the PAB, general guidelines, and hearing procedure)* C.P.O.R., Aug. 4, 1970

6. Canada. (2013). Regulatory Impact Analysis Statement, Rules Amending the Patent Rules. In *Canada Gazette*, *Part II*, Vol. 147, No. 26, 18 December 2013.

Chapter 22

Patent Cooperation Treaty (PCT)

22.01 General description of the PCT

The PCT is a multilateral treaty among States, concluded in 1970 and entered into force on January 24, 1978. Canada became bound by the PCT on January 2, 1990.

The PCT establishes a system of international cooperation under which an applicant can initiate patent protection procedures in several countries by filing **one** "international application". The PCT is a patent filing procedure only and does not provide for the granting of patents. The granting of patents is the responsibility of each individual member countries (Contracting States).

Under PCT, Canadians seeking patent protection in several countries can file an international application, in a standardized format in either French or English, in the Patent Office. Filing an international application has the same effect as if a regular national application was filed in each member countries where the applicant desires patent protection.

As of January 1st, 2004, PCT had 123 Contracting States.

A list of the Contracting States is available from the World Intellectual Property Organization (WIPO) Web site at:

http://www.wipo.int/pct/guide/en/

Further useful material is contained in the Treaty itself, in the PCT Applicant's Guide, in the PCT Receiving Office Guidelines, PCT Search Guidelines and PCT Preliminary Examination Guidelines, and in the Administrative Instructions. The PCT Applicant's Guide may be consulted in the CIPO library. All these publications are available from the World Intellectual Property Organization (WIPO) Web site at:

http://www.wipo.int/pct/en/index.html

The PCT Applicant's Guide can be found under "PCT Filing (Forms, Fees, etc.)". The PCT Treaty, Regulations, Administrative Instructions, PCT Receiving Office Guidelines, PCT International Search Guidelines and PCT International Preliminary Examination Guidelines can be found under "PCT Legal Texts".

22.01.01 PCT definitions

The following terms frequently used in the PCT text are defined as follows:

a) **Receiving Office** means the office where the nationals or residents of a PCT contracting state can file international applications. For Canadian nationals, applications may be filed with the Patent Office or the International Bureau;

b) **International Bureau (IB)** means the International Bureau of the World Intellectual Property Organization (WIPO) in Geneva;

c) **Contracting States** means the states party to the PCT which include almost every industrialized country of the world;

d) **Designated Office** means the national office designated by an applicant under Chapter I;

e) **Elected Office** means the national office elected by an applicant under Chapter II;

f) **International Searching Authority (ISA)** means one of the offices responsible for establishing International Search Reports (ISR) and the first written opinion on patentability by the ISA; and

g) **International Preliminary Examining Authority (IPEA)** means the office that carries out the international preliminary examination and the preparation of International Preliminary Reports on Patentability (IPRP [Chapter II]) under Chapter II.

A list of the ISA and IPEA States is available from the World Intellectual Property Organization (WIPO) Web site at ("X" in columns D and E):

http://www.wipo.int/pct/guide/en/

22.02 Usefulness of the PCT for applicants

Under the PCT, an applicant files a single application which designates a number of states or regions where protection is sought. The effect of filing an international application is equivalent to filing a separate application in each of the designated states/regions. Additionally, the PCT provides an International Search Report (ISR) and International Preliminary Report on Patentability (IPRP) for each international application. The ISR and IPRP provide the applicant with invaluable information to evaluate the likelihood of obtaining patents in the designated states or regions.

If an applicant decides to continue the international application to obtain national (or regional) patents, he or she can wait until the end of the 30th month (31st month in some states or regions) after the filing of the international application (or of an earlier application for which priority is claimed). The following states are exceptions (as of July 2004):

Table 22.1: Transitional Reservation Countries under PCT Article 22

State	Time limit for National Phase Entry under PCT Article 22(1)	Regional patent alternative
CH – Switzerland	20 months	EPO – 31 months
FI – Finland	20 months	EPO – 31 months
LU – Luxembourg	20 months	EPO – 31 months
SE – Sweden	20 months	EPO – 31 months
TZ – United Republic of Tanzania	21 months	ARIPO – 30 months
UG – Uganda	21 months	ARIPO – 30 months
ZM – Zambia	20 months	ARIPO – 30 months

Updated information regarding this list of exceptions, is available from the World Intellectual Property Organization (WIPO) Web site at:

http://www.wipo.int/pct/en/texts/reservations/res_incomp.pdf

Notwithstanding the above noted list of countries in table 22.1, it is noted that all those remaining states are covered by a regional designation, i.e. either under an African or European regional designation. Therefore, although these countries are the only remaining designated Offices that have not withdrawn their notification of incompatibility, in effect, applicants in these remaining countries can always enter the regional phase within the time limit of 31 months under PCT Article 22 (3). That is to say, the thirty-month (or 31 month) time limit for entry into the national or regional phase is now possible in respect to ALL PCT contracting states.

The applicant may optionally request an international preliminary examination resulting in an International Preliminary Report on Patentability by the IPEA (IPRP [Chapter II]). If the international preliminary examination is requested before the end of 19 months after the filing of the international application or of an earlier application for which priority is claimed, the applicant may delay the national phase of patent prosecution for the Transitional Reservation Countries (see Table 22.1 above) by 10 months.

The deferral of the entry into the National Phase gives applicants time to consider the patentability opinion obtained in the International Preliminary Report on Patentability (IPRP) and to decide whether to start costly patent granting procedures in foreign countries. The translation into other languages, payment fees in foreign currencies, and the appointment of foreign patent agents, all costs associated with filing separate applications, is postponed. It also provides the applicant with more time to find a licensee or a partner before entering in the costly national/regional phases.

A table of Chapter I and II time limits for each state/region is available from the World Intellectual Property Organization (WIPO) Web site at:

http://www.wipo.int/pct/en/index.html

Follow the link on "Time Limits for Entering National/Regional Phase Under PCT Chapters I and II..."

When the international preliminary examination is demanded, a written opinion during the international examination process can be drafted from the first written opinion by the ISA, if the IPEA considers that it is still relevant.

22.03 The international phase for processing an international patent application

International Phase

i) **Filing of the international application:** The applicant files a single international application in a single language accepted by a Receiving Office and pays the prescribed fees to this Receiving Office. That application has the effect of a regular national application in all designated states (PCT Contracting States) where protection is sought.

ii) **International Search Report:** After conducting a prior art search, the ISA must establish an International Search Report and a first written opinion before the expiry of 16 months from either the priority date of the international application, or the international filing date if no priority is requested.

iii) **Publication of international applications:** The IB publishes the international application, any amendments, and the search report on the "publishing Tuesday" (WIPO publishes applications on alternate Tuesdays) following the expiry of the 18-month period from either the priority date of the international application, or the international filing date, if no priority is requested.

v) **International Preliminary Report on Patentability (IPRP):** The applicant has the option to demand an international preliminary examination under Chapter II of the Treaty (which postpones the entry to the national phase, before the elected Offices for the Transitional Reservation Countries listed in table 22.1 of MOPOP, which results in an International Preliminary Report on Patentability prepared by the IPEA (IPRP [Chapter II]). When the international preliminary examination is not demanded, the Internal Bureau issues an International Preliminary Report on Patentability based on the first written opinion on patentability by the ISA (IPRP [Chapter I]) and optionally with comments on this opinion by the applicant. While the designated or elected offices are not bound to follow the conclusion of the IPEA or ISA, the report contains a good indication of the chances of obtaining the desired protection for the invention.

22.04 Processing by the Receiving Office

The Receiving Office carries out the following functions:

a) receives the international application and the related fees and notifies the applicant of the receipt of the international application indicating the date of actual receipt and the international application number e.g., PCT/CA2004/123456 (see PCT Rule 20.5(c) and PCT Gazette No. 47/2001, November 22, 2001, pp. 21585 and 21586).

b) checks the international application to determine whether it meets the requirements prescribed by the PCT (Article 11 and Rule 11 of the PCT) as to form and content (the checks performed by the Receiving Office are of a formal nature and do not consider the substance of the invention);

c) communicates with the applicant in order to obtain corrections where the international application does not meet certain requirements as to fees, form and content;

d) accords the international filing date, where possible; and

e) transmits copies of the international application and other related documents to the ISA and to the IB.

22.04.01 Requirements to obtain an international filing date

For a PCT application filed in Canada, the Receiving Office (CIPO) must accord as the "international filing date" the date of receipt of the international application provided that at the time of receipt:

a) at least one of the applicants is a resident or national of Canada;

b) the international application is in English or French (only one copy is necessary); and

c) the international application contains at least the following elements:

(i) an indication that it is intended as an international application;
(ii) the name of the applicant;
(iii) a part which appears to be a description; and
(iv) a part which appears to be a claim or claims (Article 11(1) of PCT).

When none of the applicants is a resident or national of Canada, the international application is forwarded to the IB, and the international filing date will be the date the Canadian Receiving Office had received the international application provided that the material originally submitted, according to the IB, satisfies the mandatory requirements to obtain an international filing date,

The filing forms are available from the World Intellectual Property Organization (WIPO) Web site at:

http://www.wipo.int/pct/en/forms/index.htm

A software created to assist the applicant in filing the PCT forms and for filing the application electronically, along with the supporting documentation are available from the World Intellectual Property Organization (WIPO) Web site at:

http://www.wipo.int/pct-safe/en/index.htm

Since January 2nd, 2004, the Patent Office, as a receiving office, will accept Request forms created with the pct-safe software. Applicant should consult periodically CIPO's What's new website at:

http://strategis.gc.ca/sc_mrksv/cipo/new/new-e.html

for further notice regarding international patent application filing.

When an international application does not, at the time of receipt, fulfill the above requirements, the Receiving Office invites the applicant to file the required correction and fixes a reasonable time limit. If the correction is made within the time limit, the date of receipt of the required correction becomes the international filing date.

When an application refers to drawings in the description but the drawings are not included, the Receiving Office notifies the applicant. In this situation, the international filing date which will be accorded to the application is the date on which the missing drawings are received (Article 14(2) of PCT).

For purposes of the Paris Convention, the filing of an international application has the effect of filing a regular national application in each designated State. Priority rights, for example, may be based on an international application (Article 11(4) of PCT).

22.04.02 Fees associated with filing an international application

Four types of fees are payable to a Receiving Office when an applicant files an international application:

1. Transmittal fee (PCT Rule 14)

   The transmittal fee is retained by the Receiving Office for receiving and checking the international application, and for transmitting copies of it to the IB and the ISA.

2. International filing fees (PCT Rule 15)

   The international filing fee accrues to the IB for doing the central docketing and for publishing the international application. There is a supplementary charge for each page over 30 pages in the application.

3. Search fee (PCT Rule 16)

   The search fee accrues to the ISA for carrying out the search and issuing an International Search Report.

4. Fee for priority document (PCT Rule 17.1 (b))

   The fee for priority document accrues to receiving Office for the service of transmitting certified copy of earlier application the priority of which is claimed.

All fees, with the exception of fee for priority document, should be paid when the international application is filed, but are payable within one month after filing in order to maintain the original filing date. Fees for priority document can be paid at the latest before the expiration of 16 months from the priority date, after which the receiving Office may consider the request under PCT Rule 17.1 (b) as not having been made.

The search and international filing fee which accrue to the ISA and IB respectively may change as exchange rates fluctuate. A schedule of fees applicable to the PCT is published as item 13 in the CPOR and is available from the CIPO Web site at:

http://napoleon.ic.gc.ca/cipo/patgazarc.nsf/v_currentedition_e/notice/$File/notice.pdf?OpenElement

22.04.03 Elements of an international application

The structure of an international application is governed by the Treaty and particularly the Treaty Regulations. The Patent Office is bound by the PCT provisions and cannot require the correction of non-compliance to formalities not expressly provided for in the Treaty.

Under Article 3, the Treaty specifies that an international application must be in a prescribed language (PCT Rule 12); therefore, international applications filed in Canada as a Receiving Office must be submitted either in English or in French. The international application must also comply with the prescribed physical requirements (PCT Rule 11) and the unity of invention requirements (PCT Rule 13). It is also subject to prescribed fees.

The international application must contain a

- request (PCT Rule 4)
- a description (PCT Rule 5) with, when required, sequence listing(s) (PCT Rule 5.2)
- claim(s) (PCT Rule 6)
- drawing(s) (PCT Rule 7) (when required), and
- an abstract (PCT Rule 8).

22.04.04 Designation of countries and its effect (PCT Rule 4.9)

The filing of an international application along with the request, constitutes the designation of all Contracting States that are bound by PCT on the international filing date (Rule 4.9(a) of PCT). Furthermore, this full designation is an indication that the international application is, for some designed states (see Article 43 and 44 of the PCT), for the grant of every kind of protection which is available by way of the designation of that state, such as inventor's certificates, utility certificates or models, patents or certificates of addition, inventor's certificate of addition, or utility certificate of addition.

The designation of some Contracting States (currently, Germany, South Korea and Russia) can be waived in view of some national laws restrictions. The applicant can unselect such state by checking the appropriate box in Box No. V of the PCT Request (Request Form).

This full designation postpones the final decision on which States will be retained for patent protection until the end of the international phase. This procedure gives the applicant more time to consider the various deadlines (formal national phase deadline, translation, power of attorney...) dictating the entry into the national phases. The selection of the Contracting States to be covered is effected by entering in the national phase in the countries or region of interest for the applicant. However, the applicant has to consider to elect the Transitional Reservation Countries (table 22.1) by filing a Chapter II demand, before the expiration of 19 months of the priority date (transitional measure), to enter into National phase in these countries at the end of 30 or 31 months, otherwise the applicant will have to enter into National phase at the end of 20 or 21 months.

22.05 Processing by the International Bureau

The IB administers the Treaty. The main procedural steps that an international application goes through at the IB are the following:

a) the IB monitors and keeps the "record copy" of international applications and all papers filed by applicants;

b) the applicant may amend the claims of the international application under Article 19 by means of communications addressed to the IB;

c) the IB communicates the international application only upon request and at the time specified by the designated and elected Offices (PCT Rule 93*bis*);

d) the IB publishes the international application and International Search Report with a publication number (e.g. WO2004/654321) which shall be different from the international application number (e.g. PCT/CA2004/123456); and

e) If a demand for international preliminary examination is filed, the IB furnishes the international preliminary report on patentability (IPRP [Chapter II]) upon request to an elected Office (PCT Rule 94). and makes a translation of that report into English when required. The IB also notifies the Transitional Reservation Countries (Table 22.1) of their election.

If no demand for international preliminary examination is filed, the IB issues an International Preliminary Report on Patentability by the ISA (IPRP [Chapter I]), and makes publicly available this report 30 months from the earliest priority date of the international application. An informal procedure is provided for the applicant to submit comments on the ISA written opinion on patentability. These comments are made publicily available along with the IPRP [Chapter I].

22.05.01 Amendment of claims before the International Bureau (Article 19)

After receiving the International Search Report (see MOPOP 22.03.11), the applicant has the right under PCT Chapter I (PCT Article 19 and PCT Rule 46) to amend the claims, and only the claims, once. The time limit for making an amendment is normally 2 months after the search report is transmitted to the applicant, but may be extended to 3 months if the report is transmitted before 14 months from the priority date. Any such amendment must be filed with the IB.

The amendments shall not go beyond the description in the international application as filed i.e., no new matter may be added. Amendments may be made either by cancelling one or more entire claims, by adding one or more new claims and/or by amending the text of one or more of the claims as filed. Where a claim is cancelled, no renumbering of the other claims is required.

If the applicant wishes to amend the claims by changing the existing claims or cancelling entire sheets of claims, he or she must supply replacement sheets and a letter drawing attention to the differences between the replaced sheets and the replacement sheets. The applicant may, at the same time, file a brief statement under Article 19 of the PCT, explaining the amendments and indicating any impact that such amendments might have on the description and the drawings.

22.05.02 International publication

The IB publishes the international application, any amendments, and the International Search Report in the form of a pamphlet (PCT Rule 48.1(a)) as soon as possible after 18 months from the priority date of the application. However, an applicant may ask the IB to publish the international application earlier (PCT Rule 48.4). When the international application is withdrawn by the applicant before the completion of the technical preparations for publication, the international publication can be prevented (PCT Rule 90*bis*(c)).

If the International Search Report and any amendment under Article 19 are not available at the time of publication, they are published separately after they have been received by the IB. The pamphlet is printed in one of the seven following languages: English, French, Chinese, German, Japanese, Russian or Spanish. The abstract, title and search report always appear in English.

22.06 Processing by the International Searching Authority (ISA)

Every international patent application is subjected to an international search by an ISA. The objective of the international search is to discover relevant prior art for the purpose of assessing novelty and inventive step.

The international standards are prescribed in the PCT for the minimum documentation to be consulted.

The ISA carries out the following functions:

a) conducts search of claimed inventions;

b) checks for unity of invention and requests additional fees if unity is lacking;

c) establishes the International Search Report;

d) establishes a first written opinion on patentability;

e) establishes a title and an abstract if either is missing or is inadequate; and

f) transmits copies of the International Search Report to the IB and the applicant.

Presently, the Commissioner of Patents is the ISA for PCT international patent applications filed by Canadian residents or nationals in Canada or with the International Bureau. For international patent applications filed prior to July 26, 2004, the European Patent Office (EPO) was and remains the ISA for the application. Articles 15 to 18 of the PCT and PCT Rules 25 and 33 - 45 concern the competent ISA and its responsibilities.

22.06.01 Excluded subject matter and unity of invention

An ISA is not required to search an international application if the subject matter of the claims constitutes an excluded subject as specified under PCT Rule 39. The excluded subject matter are:

a) scientific and mathematical theories;

b) plant or animal varieties or essential biological processes for the production of plants and animals, other than microbiological processes and the products of such processes;

c) schemes, rules or methods of doing business, performing purely mental acts or playing games;

d) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods;

e) mere presentations of information; and

f) computer programs to the extent that the ISA is not equipped to search prior art concerning such programs.

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. The ISA is responsible for reviewing the claims for unity of invention (Article 17(3)(b) and PCT Rules 13 and 40). If the ISA finds unity of invention is lacking, it invites the applicant to pay additional fees. This request for additional fees produces one of the following three results:

a) The applicant willingly pays the additional fees and the ISA establishes a search report for all claims.

b) The applicant pays the additional fees under protest. A special ISA board will review the protest and this review can result in a total or partial reimbursement of the additional fee, or in a rejection of the protest. Depending on the outcome of the review, a search report will be established for the appropriate claims.

c) The applicant does not pay the additional fees. The ISA establishes a search report with respect to the main invention only.

22.06.02 International Search Report (ISR)

The results of the international search are recorded in the International Search Report, which is transmitted to the applicant and to the IB for publication (Article 18 of the PCT). The International Search Report must be established within three months from the receipt of the search copy by the ISA or nine months from the priority date, whichever time limit expires later (Rule 42 of the PCT). Presently, the International Search Report for international applications filed in Canada is established by the EPO in either English or French, depending upon the language used in the application. As of July 26, 2004, the Commissioner of Patents is the ISA for PCT international patent applications filed in Canada or filed in the International Bureau by Canadian nationals or residents on or after that date.

The report identifies the application concerned by its number, the name of the applicant, the international filing date, the priority date (if any), the date of the report, the international patent classification, the fields searched, and the documents constituting the relevant prior art (Rule 43 of the PCT).

The documents are cited against claims to which they are relevant. The report indicates subject matter not searched because of lack of unity of invention, and applicant's failure to pay additional search fees.

The report also contains a copy of any title or abstract that may have been either revised or established by the ISA.

The International Search Report is always translated into English unless it was originally established in English (Rule 45 of the PCT).

22.07 Processing by the International Preliminary Examining Authority (IPEA)

International preliminary examination of an international application may be requested under Chapter II of the PCT to obtain an international preliminary examination. During this procedure, at least one written opinion is issued by the IPEA. Several written opinions may be issued by the IPEA if sufficient time is available. The applicant will have the opportunity to file amendments to the description, the drawings and the claims and to provide arguments for each of the written opinions.

The international preliminary examination starts according to the schedule provided in PCT Rule 69.1

69.1 Start of International Preliminary Examination

(a) *Subject to paragraphs (b) to (e), the International Preliminary Examining Authority shall start the international preliminary examination when it is in possession of all of the following:*
  (i) *the demand;*
  (ii) *the amount due (in full) for the handling fee and the preliminary examination fee, including, where applicable, the late payment fee under Rule 58bis.2; and*
  (iii) *either the international search report and the written opinion established under Rule 43bis.1 or a notice of the declaration by the International Searching Authority under Article 17(2)(a) that no international search report will be established;*

provided that the International Preliminary Examining Authority shall not start the *international preliminary examination before the expiration of the applicable time limit under Rule 54bis.1(a) unless the applicant expressly requests an earlier start.*

(d) If the national Office or intergovernmental organization that acts as International Searching Authority also acts as International Preliminary Examining Authority, the international preliminary examination may, if that national Office or intergovernmental organization so wishes and subject to paragraphs (d) and (e), start at the same time as the international search.

(b-bis) Where, in accordance with paragraph (b), the national Office or intergovernmental organization that acts as both International Searching Authority and International Preliminary Examining Authority wishes to start the international preliminary examination at the same time as the international search and considers that all of the conditions referred to in Article 34(2)(c)(i) to (iii) are fulfilled, that national Office or intergovernmental organization need not, in its capacity as International Searching Authority, establish a written opinion under Rule 43bis.1.

(e) Where the statement concerning amendments contains an indication that amendments under Article 19 are to be taken into account (Rule 53.9(a)(i)), the International Preliminary Examining Authority shall not start the international preliminary examination before it has received a copy of the amendments concerned.

(f) Where the statement concerning amendments contains an indication that the start of the international preliminary examination is to be postponed (Rule 53.9(b)), the International Preliminary Examining Authority shall not start the international preliminary examination before whichever of the following occurs first:

- *(i) it has received a copy of any amendments made under Article 19;*
- *(ii) it has received a notice from the applicant that he does not wish to make amendments under Article 19; or*
- *(iii) the expiration of the applicable time limit under Rule 54bis.1(a).*

(e) Where the statement concerning amendments contains an indication that amendments under Article 34 are submitted with the demand (Rule 53.9(c)) but no such amendments are, in fact, submitted, the International Preliminary Examining Authority shall not start the international preliminary examination before it has received the amendments or before the time limit fixed in the invitation referred to in Rule 60.1(g) has expired, whichever occurs first.

An applicant who is a resident or national of a Contracting State bound by Chapter II of the Treaty may make a demand (Demand Form) for international preliminary examination (Rule 53 of the PCT). The demand must be submitted directly with the International Preliminary Examining Authority (IPEA) (IB or Receiving Office). The demand comprises the election of all Contracting States which are designated and bound by Chapter II of the Treaty (Rule 53.7 of the PCT).

The IPEA carries out the following functions:

a) receives the demand for international preliminary examination;

b) receives both handling and preliminary examination fees;

c) checks the demand for non-compliance to formalities (conformance with Rules 53, 54 and 55 of the PCT on format of the demand, applicant entitlement and language requirement) and verifies the payment of fees;

d) sends the original copy of the demand, and handling fees to the IB.

e) examines the international application for sufficiency of description, unity of invention, support of claims by the original description, and for patentability of claims in accordance with PCT criteria;

f) issues written opinions to which the applicant may respond with amendments or arguments. Unless advised otherwise by the IPEA (PCT Rules 66.1*bis*) the first written opinion by the ISA is to be considered as a written opinion of the IPEA for the purposes of PCT Rule 66.2(a):

g) prepares the International Preliminary Report on Patentability [Chapter II]; and

h) transmits the report to the IB and the applicant.

Presently, the Commissioner of Patents is the IPEA for PCT international patent applications filed in Canadian residents or nationals in Canada or with the International Bureau. For international patent applications filed prior to July 26, 2004, the European Patent Office (EPO) was and remains the IPEA for the application. Articles 31 - 42 and

Rules 53 - 78 of the PCT concern the IPEA and its responsibilities.

22.07.01 Fees associated with international examination

There are two kinds of fees which have to be paid in connection with a demand for an international preliminary examination:

1. The preliminary examination fee
   This fee accrues to the IPEA, mainly for carrying out the international preliminary examination and for establishing the report.

2. The handling fee
   This fee accrues to the IB for carrying out various tasks.

Where the IPEA finds that insufficient handling or preliminary examination fee have been paid, the IPEA invites the applicant to pay the amount required to cover the insufficient fee, together with, where applicable, a late payment fee under Rule 58*bis*.2 of the PCT, within a time limit of one month from the date of the invitation.

22.07.02 Amendments before the IPEA (Article 34)

Any applicant contemplating making a demand for preliminary examination may choose not to amend the claims after receiving the International Search Report under the provisions of Article 19 of the PCT. The applicant may rather choose to wait and submit amendments to the IPEA together with the demand, and/or amend the application after receiving a written opinion from the IPEA. At this stage, the applicant may amend not only the claims, but other parts of the application as well (Article 34 and Rule 66 of the PCT). The amendments may not go beyond the description of the international application as filed i.e., no new matter may be added.

The applicant may have several opportunities to amend the international application during the preliminary examination process, depending on the time available. The limiting factor is the PCT requirement that the IPEA complete the international preliminary examination report before the expiry of 28 months from the priority date, or 28 months from the international filing date, if there is no priority date.

Amendments are made by providing replacement sheets, accompanied by a letter of explanation. The amendment(s) and letter(s) must be in the language in which the international application was filed (Rule 66 of the PCT).

22.07.03 Excluded subject matter and unity of invention

Claims relating to inventions in respect of which no International Search Report has been established, because the claims relate to excluded subject matter or do not meet the requirements for unity of invention, will not be the subject of international preliminary examination. This will be indicated in any written opinion as well as in the international preliminary examination report.

When the IPEA considers that the international application does not comply with the requirements of unity of invention (Article 34(3) and Rule 68 of the PCT), it may choose between two courses of action:

1) it may carry out the international preliminary examination on the entire international application and express its views on the lack of unity of invention in the report; or

2) it may invite the applicant to restrict the claims so as to comply with the requirement or pay additional fees. The request for additional fees produces one of the following four results:

a) The applicant restricts the claims as required, in which case the examination is carried out on the claims as restricted;

b) The applicant willingly pays the additional fees and the international examination is carried out on the claims for the main invention and on the claims in respect of which additional fees have been paid (Rule 68.2 of the PCT);

c) The applicant pays the additional fees under protest; in this case, a special IPEA Board will review the protest. This review can result in a total or partial reimbursement of the additional fees, or in a rejection of the protest. Depending on the outcome of the review, an examination report will be established for the appropriate claims (Rule 68.3 of the PCT);

d) The applicant neither restricts the claims nor pays additional fees, in which case, the examination is carried out on the main invention as identified by the IPEA or the applicant (Article 34(C) of the PCT).

22.07.04 International Preliminary Report on Patentability [Chapter II]

Following the international preliminary examination procedure, an International Preliminary Report on Patentability (IPRP [Chapter II]) is issued at whichever of the following periods expires last (Rule 69.2 of the PCT):

(i) 28 months from the priority date;

(ii) six months from the time provided under Rule 69.1 (see MOPOP 22.07) for the start of the international preliminary examination; or

(iii) six months from the date of receipt by the International Preliminary Examining Authority of the translation furnished under Rule 55.2.

The international preliminary examination report is a *non-binding opinion* on the patentability of the claims. Under PCT Rule 70, the international preliminary examination report includes:

a) identification of the IPEA and the applicant;

b) the applicable dates;

c) the basis of the report;

d) a simple yes or no statement with respect to each claim indicating whether the claims are thought to satisfy the criteria of patentability (novelty, inventive step and industrial applicability) and including an explanation and citation of references to support the conclusion contained in the statement;

e) the citation of certain published documents comprising applications or patents published after the international filing date but filed prior to the international filing date (prior art effect);

f) mention of certain defects under Article 34(4) and Rule 66.2 of the PCT;

g) remarks concerning unity of invention; and

h) an annex of any amendments filed during the examination process.

The report will express no opinion as to whether the claims are patentable under the national law of any elected country.

22.08 The national phase for processing an international application

On completion of the international phase, further action is required in order to obtain patent protection in the various countries designated in the international application at the time of filing. The applicant has to enter the **"national phase"**, that is, initiate patent granting procedures in each designated or elected country according to the laws, rules and jurisprudence thereof.

22.08.01 Entry into the national phase in Canada

In order to obtain patent protection in the various countries designated in the international application at the time of filing, the applicant has to enter the national phase, that is, initiate patent granting procedures in each designated country and pay the prescribed national fees.

Applicants must comply with the terms of the PCT and the regulations under the PCT as well as Part II of the Canadian Rules respecting the Patent Act. The national phase starts only if the applicant fulfills certain requirements, either before the expiration of a certain time limit or together with an expressed request that it starts earlier. The applicant should not expect any notification inviting him to fulfill those requirements. He has the sole responsibility for fulfilling them in due time [1].

Part II of the Canadian Rules respecting the *Patent Act* provides a connection between the Patent Cooperation Treaty and the Canadian *Patent Act*. It covers such items as time limits, language of applications, fees and terms and conditions relating to the national phase.

The effective filing date of a PCT national phase application is the international filing date, and not the date on which the PCT application enters the national phase in Canada.

To enter the national phase in Canada, an applicant must take steps to do so within 30 months from the priority date of the international application, or 30 months from the international filing date if no priority is claimed (paragraph 58(3)(*a*) of the *Patent Rules*).

When an international application becomes a PCT national application, the application shall thereafter be deemed to be an application filed in Canada [2] and the *Patent Act* and the *Patent Rules* shall thereafter apply in respect of that application (section 59 of the *Patent Rules*).

For the purposes of a citation under section 28.2(1)(*c*) and (*d*) of the *Patent Act* in the prosecution of another application, a PCT application will benefit from its filing date or priority date only after it has entered the national phase.

Under section 61 of the *Patent Rules*, the requirement that an application contain a petition does not apply to PCT national phase applications. The first page of the pamphlet published by the IB includes all the required information to enter the national phase.

22.08.02 Late entry into the national phase in Canada

Under subsection 58(3)(*b*) of the *Patent Rules*, where an applicant fails to enter the national phase within 30 months after the priority date, but pays the additional fee for late payment and the required maintenance fees (set out in Schedule II, item 11 of the *Patent Rules*), he/she may enter the national phase up to 42 months after the priority date.

22.08.03 Content of PCT national phase application entering under Chapter I in Canada

When an international application becomes a PCT national phase application by entering the national phase in Canada under Chapter I of PCT, i.e., when no demand under Chapter II has been filed (IPRP [Chapter II]), the Patent Office creates an examiner's file comprising:

a) a copy of the applicant's international application as communicated to the Patent Office by the IB;

b) a copy of the International Search Report or, alternatively, a statement by the ISA that no search report will be established (Article 17(2)(a) of the PCT);

c) a copy of any amendment to the claims, and any statement made by the applicant under PCT Article 19 in light of the international search; and

d) a copy of the IPRP [Chapter I]

If the international application was published by the IB in a language other than English or French, the examiner's file must include the translation into either French or English which should have been provided by the applicant upon entering the national phase in Canada. The translation must correspond to the international application as filed or as amended during the international phase. If the translation corresponds to the application as filed, a translation of any amendments submitted during the international phase can be filed separately or incorporated in the translation of the Canadian application.

If the Commissioner has reasonable grounds to believe that the translation is not accurate, the Commissioner shall requisition the applicant to provide a statement by the translator to the effect that, to the best of the translator's knowledge, the translation is complete and faithful (subsection 58(4) of the *Patent Rules*).

22.08.04 Content of PCT national phase application entering under Chapter II in Canada

When an international application becomes a PCT national phase application by entering the national phase in Canada under Chapter II of the PCT, the examiner's file should include the following:

a) a copy of the applicant's international application as communicated to the Patent Office by the IB;

b) a copy of the International Search Report or, alternatively, a statement by the ISA that no search report will be established (Article 17(2)(a) of the PCT);

c) a copy of any amendment to the claims, and any statement made by the applicant under PCT Article 19 in light of the international search;

d) a copy of the IPRP [Chapter II]; and

e) a copy of replacement sheets containing amendments, if any.

All of the above items must be presented in either French or English.

If an applicant believes that he/she is entitled to claim status as a “small entity” as defined under section 2 of the *Patent Rules*, a formal declaration of the status as small entity at the international filing date, has to be provided at the National Entry.

Furthermore, if the applicant enters the national phase in Canada more than two years after the international filing date, the applicant must also pay the first maintenance fee at the time of entry (subsection 58(2) of the *Patent Rules*).

22.08.05 Other amendments provided on or after national entry in Canada

Under the terms of PCT, the applicant may amend the description, the claims and the drawings before national entry into any designated or elected Office (Articles 19 and 41 of the PCT).

However, once a PCT application enters the national phase in Canada, it is treated in exactly the same manner as any other application filed in Canada. Therefore, when a PCT national phase application includes voluntary amendments on entering the national phase which were not considered during the international phase, it must be accompanied by a written statement under section 34 of the *Patent Rules*. Moreover, voluntary amendments that are filed after the national entry on a PCT national phase application, must be accompanied by a written statement explaining the nature of the amendment and its purpose.

It is strongly suggested to use a heading such as, VOLUNTARY AMENDMENT FOLLOWING PCT NATIONAL ENTRY, on the written statement.

22.08.06 Completion requirements in the national phase in Canada

An application which has entered the national phase in Canada according to the provisions of subsection 58(1) or (2) of the *Patent Rules* may still be incomplete. To provide a complete application, subsection 62(1) of the Patent Rules specifies the following documents and information that must be provided to avoid abandonment under subsection 73(2) of the *Patent Act*:

a) the name and address of the inventor where that information has not already been provided;

b) c) Paragraphs 62(1)(*b*) and 62(1)(*c*) of the *Patent Rules* are repealed as of 30 March, 2004 (SOR/2004-67). Where a sequence listing is required by paragraph 111(a) of the *Patent Rules*, a copy of sequence listing in computer readable form complying with section 131 of the *Patent Rules* is mandatory unless the description contains a sequence listing complying with the standard provided for in the PCT Administrative Instructions (PCT Rule 13*ter*.2 of the Regulations under the PCT). However, the sequence listing portion filed electronically may not appear with the rest of the description. At laid open, a note on the cover page of the PCT publication would indicate that the sequence listing is available separately in electronic form. Applicant can provide the copy of sequence listing complying with section 131 of the *Patent Rules* at national entry, as a voluntary submission or following a notification, with the opportunity to comply within a prescribed period of time, by the Patent Office. Abandonment of the application by not complying to section 131 of the *Patent Rules* will occur only following the requisition under subsection 30(2) of the *Patent Rules* by the Patent Office, provided that the prescribed fee for the Request for examination under subsection 35(1) of the *Patent Act* has been paid. When prescribed fee for the Request for examination is not paid and the application does not comply to section 131 of the *Patent Rules*, a courtesy letter with a three (3) months delay will be sent. Failure to respond to the courtesy letter may result in a formal request, under subsection 35(2) of the *Patent Act*, by the Commissioner to the applicant to make a request for examination pursuant to subsection 35(1) of the *Patent Act*.

More information about sequence listings is available from the World Intellectual

Property Organization (WIPO) Web site at:

http://www.wipo.int/pct/en/sequences/index.htm

d) an appointment of a patent agent, where required by section 20 of the *Patent Rules*;

e) an appointment of an associate patent agent, where required by section 21 of the *Patent Rules*; and

f) an appointment of a representative, where required by section 29 of the *Patent Act*.

The date by which the information and documents referred to in subsection 62(1) of the *Patent Rules* must be submitted is the expiry of the latest of:

a) the 36-month period after the priority date; and

b) the six-month period after the applicant complies with the requirements of subsection 58(1) and, where applicable, subsection 58(2) of the Patent Rules.

No extension of the time limits given in paragraphs a), b) and c) above is permitted (subsection 62(3) of the *Patent Rules*).

The Commissioner may, at the request of the applicant, reinstate the international application which is deemed to have been abandoned if, within 12 months after the date on which it was deemed to have been abandoned, the applicant complies with the above requirements and pays the reinstatement fee (section 98(1) of the *Patent Rules*) [3].

22.08.07 Application of Canadian Legislation

Section 59 of the Patent Rules provides that when an international application becomes a PCT national phase application, the application is considered from that moment on as an application filed in Canada. The PCT national phase application is examined for its conformity to the *Patent Act* and *Rules*, which includes any substantive conditions of patentability, such as any question in respect of prior art, new matter, clarity and/or ambiguity (Article 27(5) of the PCT). The *Patent Act* and *Rules* cannot require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in the PCT Treaty and Regulations (Article 27(1) of the PCT).

The authority regarding unity of invention for all patent applications filed in Canada, including PCT application in national phase is found in section 36 of the *Patent Act*. Since the requirements under section 36 of the *Patent Act* have the same scope as those prescribed under PCT Rule 13, these requirements are not different from or additional to PCT Rule 13.1, and therefore compliant with Article 27(1) of the PCT.

Under section 38.2 of the *Patent Act*, any new matter added in a PCT national phase application after the international filing date which is not reasonably to be inferred from the originally-filed specification and drawings must be removed. Since several amendments may have been made to a PCT national phase application prior to the examiner's consideration, the examiner's report will refer to the specific matter considered as new matter and the date of introduction of this matter.

22.09 Access to the file of an international application

In addition to the international publication, which includes the international application and the International Search Report (sometimes published at a later date), third parties can access the first written opinion by the ISA, the IPRP [Chapter I] (and/or any translation thereof), or the IPRP [Chapter II] to the Canadian national phase application originating from the international application under the provision of section 10 of the *Patent Act*, but after the expiration of 30 months from the priority date (PCT Rules 44*ter* and 94).

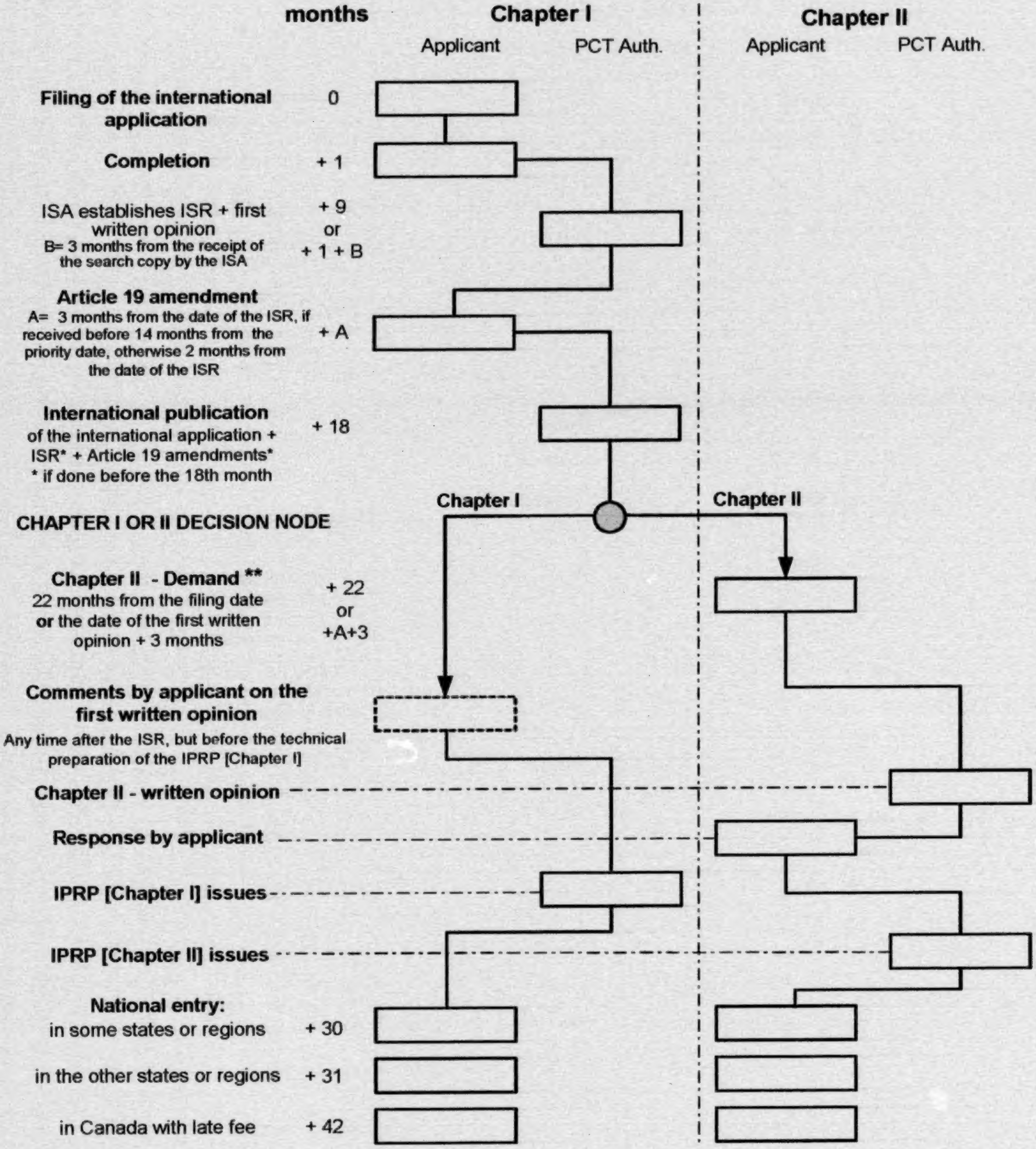
Endnotes for Chapter 22

1 PCT Applicant's Guide Volume II, Chapter 2, Paragraph 12
First Green Park Pty. v. Canada (Attorney General) (1997) 72 C.P.R. (3d) 327 at 332-333

2 Celltech Ltd. v. Canada (Commissioner of Patents) (1993) 46 C.P.R. (3d) 424 at 437, affirmed 55 C.P.R. (3d) 59. *"Since this was not done [designation of Canada], the Application was not to be dealt with under the law applicable to international applications in Canada"*

3 First Green Park Pty. Ltd v. Canada (Attorney General) (1998) 84 C.P.R. (3d) 46 at 51, affirmed (2000) 6 C.P.R. (4th) 234

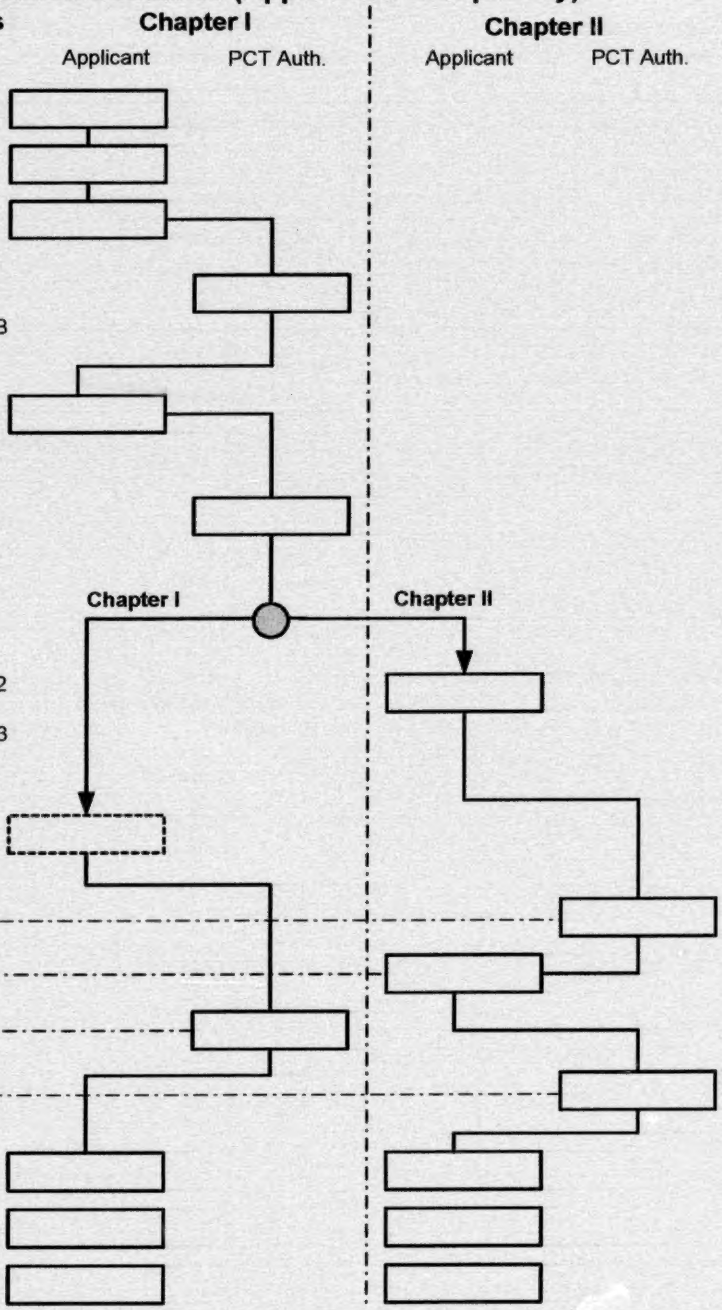
Appendix 22.1: PCT Application Deadlines (Application without priority)


months
Chapter I
Chapter II
Applicant
PCT Auth.
Applicant
PCT Auth.
Filing of the international application
0
Completion
+ 1
ISA establishes ISR + first written opinion
B= 3 months from the receipt of the search copy by the ISA
+ 9 or + 1 + B
Article 19 amendment
A= 3 months from the date of the ISR, if received before 14 months from the priority date, otherwise 2 months from the date of the ISR
+ A
International publication
of the international application + ISR* + Article 19 amendments*
* if done before the 18th month
+ 18
Chapter I
Chapter II
CHAPTER I OR II DECISION NODE
Chapter II - Demand **
22 months from the filing date or the date of the first written opinion + 3 months
+ 22 or +A+3
Comments by applicant on the first written opinion
Any time after the ISR, but before the technical preparation of the IPRP [Chapter I]
Chapter II - written opinion
Response by applicant
IPRP [Chapter I] issues
IPRP [Chapter II] issues
National entry:
in some states or regions
+ 30
in the other states or regions
+ 31
in Canada with late fee
+ 42

** + 19 for international examination and transitional reservation countries, 10-month extension (Table 22.1 of MOPOP)

Appendix 22.2: PCT Application Deadlines (Application with priority)

	months
Filing of the priority application	0 (P)
Filing of the international application (up to 12 months after P)	F
Completion	F + 1
ISA establishes ISR + first written opinion B= 3 months from the receipt of the search copy by the ISA	P + 9 or F + 1+ B
Article 19 amendment A= 3 months from the date of the ISR, if received before 14 months from the priority date, otherwise 2 months from the date of the ISR	P + A
International publication of the international application + ISR* + Article 19 amendments* * if done before the 18th month	P + 18
CHAPTER I OR II DECISION NODE	
Chapter II - Demand ** 22 months from the filing date **or** the date of the first written opinion + 3 months	P + 22 or P+A+3
Comments by applicant on the first written opinion Any time after the ISR, but before the technical preparation of the IPRP [Chapter I]	
Chapter II - written opinion	
Response by applicant	
IPRP [Chapter I] issues	
IPRP [Chapter II] issues	
National entry: in some states or regions	P + 30
in the other states or regions	P + 31
in Canada with late fee	P + 42



** P + 19 for international examination and transitional reservation countries, 10-month extension (Table 22.1 of MOPOP)

Chapter 23
Amendments to patents

23.00 Contents of chapter

This chapter deals with the various statutory methods whereby an issued patent may be amended. The topics covered include disclaimer (23.01 to 23.01.02), re-examination (23.02 to 23.02.10), reissue (23.03 to 23.03.11) and section 8 corrections (23.04 to 23.04.03).

23.01 Disclaimer

Disclaimer is a mechanism whereby a patentee may amend a patent to claim less than that which was claimed in the original patent. A disclaimer is not limited to a whole claim or claims. A part of a claim may be disclaimed, provided that the disclaimer does not extend the scope of this claim or any claims depending on this claim [1].

Subsection 48(1) of the *Patent Act* entitles a patentee to disclaim anything included in the patent by mistake, accident or inadvertence [2] at any time during the term of the patent. Whenever a specification is too broad, claiming more than the inventor invented or subject matter to which the patentee had no lawful right [3], the patentee may, on payment of a prescribed fee, disclaim such parts as the patentee does not claim to own by virtue of the patent (paragraph 48(1)(*b*) of the *Patent Act* and Schedule 2, Part 3, Item 13 of the *Patent Rules*). A disclaimer cannot be used to broaden the claims of a patent.

23.01.01 Disclaimer form

A disclaimer must follow the form and instructions for its completion as set out in Form 2 of Schedule I of the *Patent Rules* to the extent applicable (section 44 of the *Patent Rules*). In completing Form 2, the patentee must follow the precise form of items 3(1) and 3(2), which specify the subject matter disclaimed. The expression "...with the exception of the following:" in Form 2 indicates elements of the claim(s) remaining after the disclaimer, and is not to be used as a device for reformulating or redefining the invention disclosed and claimed [4].

23.01.02 Effect of a disclaimer

Disclaimers do not normally affect any court action pending at the time they are made (subsection 48(4) of the *Patent Act*). In a court action, the plaintiff has to be a party to the disclaimer to be bound by it [5]. In a comparable manner, a disclaimer filed after the notice of hearing of the Patented Medicine Prices Review Board does not affect the authority of the Board [6].

Following a disclaimer, the remaining claims are deemed to be valid for the matter not disclaimed, i.e. in their disclaimed form [7] (subsection 48(6) of the *Patent Act*). The disclaimer is unconditional. The existing claims of the patent are the claims as amended by virtue of the disclaimer, and the only invention protected by the letters patent is that defined by such existing claims [8].

23.02 Re-examination

This section describes the practice that is followed when a request for re-examination of a patent is submitted.

23.02.01 Request

Any person, including the patentee, may request re-examination of any claim or claims of a patent issued after October 1, 1989, at any time during the life of the patent on the basis of prior art only. The prior art shall consist of patents, applications for patents open to pubic inspection and printed publications only (subsection 48.1(1) of the *Patent Act*). The request, including copies of the prior art, must be provided in duplicate if the requester is not the patentee (section 45 of the *Patent Rules*). One copy is for a re-examination board and the other copy is for the patentee. The requester must set forth the pertinency of the prior art and the manner of applying it to the claim(s) for which re-examination is requested. The request must be in writing and be accompanied by the prescribed fee.

23.02.02 Notification procedure

Upon receipt of a request satisfactorily identifying the prior art and the manner of applying it, along with the fee, the Commissioner will appoint a re-examination board (RXB). The patentee will be sent a package that contains a copy of the request including the prior art and a notification identifying the composition of the re-examination board. In the event that the requester is the patentee, only a notification identifying the composition of the RXB will be sent (subsections 48.1(3) and 48.2(1) of the *Patent Act*).

23.02.03 Unacceptable request

If the request does not fulfil all of the requirements of subsections 48.1(1) and (2) of the *Patent Act* and section 45 of the *Patent Rules*, the requester will be so notified. The notification letter will detail the reasons why the request is not acceptable. An example of an unacceptable request is one that does not detail the pertinency of the prior art against the claim or claims to be re-examined. The requester will be informed by the Commissioner that no further steps will be undertaken until the above requirements have been fulfilled.

Any unacceptable requests may be resubmitted in acceptable form without the payment of a further fee.

23.02.04 Completed request

The completed request will become part of a Patent Office initial re-examination file, which will consist of the following:

a) the Patent Office file copy of the patent, including the description, claim(s), drawings as issued and all prosecution correspondence
b) a copy of the request
c) copies of the prior art being relied on
d) reasons supporting the request for re-examination

This file is open to public inspection.

23.02.05 Re-examination board

The Commissioner will establish a re-examination board consisting of not fewer than three persons, at least two of whom shall be employees of the Patent Office, to which the request shall be referred for determination (subsection 48.2(1) of the *Patent Act*). Within three months following its establishment, the re-examination board shall determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request for re-examination (subsection 48.2(2) of the *Patent Act*).

23.02.06 Refusal of re-examination

If the board determines that re-examination should not proceed because a substantial new question affecting the patentability of a claim of the patent concerned is not raised, the requester shall be so informed. The determination not to proceed is final and is not subject to appeal, either to the Commissioner or to the courts (subsection 48.2(3) of the *Patent Act*).

23.02.07 Re-examination

The re-examination board, having decided to proceed with re-examination, shall notify the patentee and give the reasons for the decision (subsection 48.2(4) of the *Patent Act*). Within three months of the date of the notice, the patentee may make submissions on the question of the patentability of the claim(s) (subsection 48.2(5) of the *Patent Act*). Re-examination will commence upon receipt of the reply or, in the absence of a reply, within three months of the date of the notice (subsection 48.3(1) of the *Patent Act*). In either case, re-examination shall be completed within 12 months of the commencement of re-examination (subsection 48.3(3) of the *Patent Act*).

The re-examination board will not consider any matter except the claims in question in view of the supplied prior art. Further, the re-examination board will not make any changes to the description part of a patent, in that there is no statuary authority for such changes. During the re-examination period, the patentee may propose amendments to the patent claims (including submission of new claims), but the scope of the claim(s) may not be broadened. Any number of separate proposals from the patentee during this period is permissible (subsection 48.3(2) of the *Patent Act*). The Commissioner will acknowledge the correspondence from the patentee but will not reply to the proposals.

23.02.08 Certificate of re-examination

Upon conclusion of re-examination, a certificate will be issued in accordance with paragraph 48.4(1)(*a*), (*b*) or (*c*) of the *Patent Act* and attached to the patent. This certificate will affect the original patent by

a) cancelling any claim of the patent determined to be unpatentable during the re-examination;

b) confirming any claim of the patent determined to be patentable; or

c) incorporating in the patent any proposed amended claim determined to be patentable.

The effect of a certificate issued in respect of a patent under subsection 48.4(3) of the *Patent Act* is as follows:

a) If the conclusion is to cancel any claim but not all claims of the patent, the patent shall be deemed to have been issued, from the date of grant, in the corrected form.

b) If the conclusion is to cancel all claims of the patent, the patent shall be deemed never to have been issued.

c) If the conclusion is to amend any claim of the patent or incorporate a new claim or new claims in the patent, the amended claim(s) or new claim(s) shall have effect, from the date of the certificate of re-examination, for the unexpired term of the patent.

The deemed results of paragraphs (a), (b) and (c) above do not take effect until the time for taking an appeal has expired under subsection 48.5(2) of the *Patent Act* and, if an appeal is taken, the above-mentioned deemed results apply only to the extent provided in the final judgment of any appeal (subsection 48.4(4) of the *Patent Act*).

The re-examination board will send a copy of the certificate to the patentee (subsection 48.4(2) of the *Patent Act*). If the requester is not the patentee, the board may also send him or her copies of the correspondence to the patentee generated during the re-examination procedure. A summary of the certificate will appear in the Canadian Patent Office Record.

23.02.09 Termination of re-examination

Upon completion of re-examination, the contents of the re-examination file created under 23.02.04 will be sent to the Patent Office storage files. The Patent Office search file will include a copy of the patent as re-examined.

23.02.10 Appeal period

The patentee receives a copy of the certificate by registered mail and may appeal the decision of the re-examination board to the Federal Court within three months of the date of mailing of the certificate (subsections 48.5(1) and (2) of the *Patent Act*).

23.03 Reissue

Reissue is a mechanism whereby a defective patent can be corrected. It may result in broader or more restricted protection, depending on the nature of the correction.

Section 47(1) of the Patent Act enables the Commissioner to replace a defective or inoperative patent (as defined by section 47(1) of the *Patent Act*) with a new patent. In order to have a patent reissued, the patentee, or "the person for the time being entitled to the benefit of a patent for an invention [9]" must make a request for reissue (Form 1) in accordance with section 43 of the *Patent Rules*, pay a prescribed fee, and surrender the defective patent on the issue of the new patent. One of the effects of the surrender is the return by the patentee of the official copy bearing the Patent Office seal (also know as the "grant copy") to the Patent Office.

In accordance with subsection 47(1) of the *Patent Act*, a patentee may apply within four years from the date of issue of a patent for the reissue of a patent that "is deemed defective or inoperative by reason of insufficient description and specification, or by reason of the patentee's claiming more or less than he had a right to claim as new, but at the same time it appears that the error arose from inadvertence, accident or mistake without any fraudulent or deceptive intention [10]". The four-year period applies to the date of the application for reissue and not to the grant of the reissued patent [11]. The reissued patent must be for the same invention as the original.

A reissue must be confined to the invention that was completely conceived and formulated by the inventor before the application for the original patent was filed, and to the invention that the patentee attempted to describe and claim in the original application but, owing to error arising from inadvertence, accident or mistake, failed to do perfectly [12]. Further, whenever a reissue contains claims that are broader than the claims in the original patent, they must be directed to what the patentee was attempting to protect in the original patent. The scope of the reissue must not go beyond the invention as disclosed in the original patent [13].

23.03.01 Division of a reissue application

Under subsection 47(3) of the *Patent Act*, a patentee may file separate applications for reissue in respect of distinct parts of the invention covered by the original patent being reissued. Reissue applications must be filed in the Patent Office within four years from the date of issue of the original patent. The separate reissue applications must all have been filed before the effective date of surrender of the original patent grant, i.e. before the grant of a reissued patent based on any one of them.

The Commissioner will not call for division of a reissue application under subsection 36(2.1) of the *Patent Act* nor will a patentee be permitted to use the provisions of subsection 36(2) of the *Patent Act* during the reissue process under section 47 of the *Patent Act*.

23.03.02 Reissue of a reissued patent

A reissued patent may itself be reissued provided that the application to reissue is filed within four years of the date of the original patent (not of the reissued patent), and provided that the invention is that for which patent protection was sought in the original patent. A reissued patent may not be withdrawn after it has been issued in favour of the original patent.

23.03.03 Reissue and new matter

The patentee must not add new subject matter that was not part of the original invention to the description [14]. Subject matter that is properly inferable from the original specification or drawings and could have been entered under subsection 38.2(2) of the *Patent Act* may be accepted. Under subsection 38.2(3) of the *Patent Act*, drawings may be amended to add matter reasonably inferable from the original specification or drawings [15] or from matter that is admitted to be prior art or common knowledge [16]. New matter discovered after the date of the filing of the original application may not be added by reissue, as there was no attempt to protect such subject matter in the original patent.

23.03.04 Claims in reissued patent

Not only may a patentee claim less than what was claimed in the original patent, but the patentee may also claim more. In both instances the following conditions must be complied with:

a) The new claims must be directed to the same invention that the patentee attempted to protect in the original patent [17].

b) There must not have been a complete failure to describe in the original patent the invention that is the subject matter of the new claims. The claims presented in the reissue must have support in the specification of the patent [18].

23.03.05 The petition for reissue

The petition must set out fully the respects in which the patent is defective or inoperative and how the errors arose (see section 43 and Schedule I, Form 1 of the *Patent Rules*).

Reissue applications are subject to examination and are given priority of examination. Examination takes place without a request for examination or the payment of an examination fee; these are included in the reissue fee. The first step, before any other consideration, is to examine the petition for its compliance with section 47 of the *Patent Act*.

a) If the petition for reissue is acceptable, the reissue specification is subject to examination (see section 23.03.10).

b) If the petition for reissue is not acceptable, the patentee will be informed by a Commissioner's letter, which will set out the reasons for non-compliance with the *Patent Act*. The Commissioner's letter is written under subsection 47(1) of the *Patent Act* and will specify a three-month time limit for response, after which the Commissioner may refuse the reissue application.

Parts 3, 4 and 5 of Schedule I, Form 1 may not be amended after the petition for reissue is filed, other than to correct simple typographical errors obvious from the document itself. If additional evidence supporting the facts presented in the petition is submitted, it may be put on file but not added to the petition itself. If the facts presented in parts 3, 4 and 5 of the petition subsequently prove to be incorrect, the only way to make corrections is to file a completely new application for reissue (if time still permits) and to pay the reissue fee. Section 47 of the *Patent Act* does not provide for amendments of the petition and submission of additional evidence.

When items 3, 4 and 5 of the petition for reissue are not in accordance with subsection 47(1) of the *Patent Act*, no amendment may be made thereto. However, the patentee may submit a reasoned statement showing how the petition for reissue is in compliance with the *Patent Act* and/or file a new petition along with a further reissue fee provided that the four-year time period has not passed. On receipt of a Commissioner's letter indicating that the petition for reissue is not acceptable and setting a three-month period for reply, any of the following may occur:

a) If the patentee replies within the time provided, but the Commissioner, after consultation with the Patent Appeal Board (PAB), has reasonable grounds to believe that the petition for reissue still does not comply with the *Patent Act*, the Commissioner will refuse to issue a new patent and the original patent will be returned to the petitioner.

b) If the patentee replies within the time provided, and the submitted reasoned statement is found persuasive, the reissue specification is examined (see section 23.05.10).

c) If the patentee files a new petition along with a further reissue fee and submits a reasoned statement regarding the original reissue application, paragraphs (a) and (b) apply to the original reissue application. Considerations regarding the new reissue application will be addressed on their own merits.

d) If the patentee does not reply within the time provided, the Commissioner will refuse to issue a new patent and the original patent will be returned to the petitioner.

e) If the patentee files a new petition along with a further reissue fee and does not reply within the time provided for the original reissue application, the Commissioner will refuse to issue a new patent based on the original reissue application and the original patent will be transferred to the new reissue application for consideration. Considerations regarding the new reissue application will be addressed on their own merits.

23.03.06 Acceptable reasons warranting reissue (Item 3, Form 1)

The fundamental questions to be considered in deciding whether a reissue is warranted are as follows:

a) whether or not a bona fide mistake was made, resulting in a failure to obtain protection for the invention actually made by the inventor

b) whether or not there was a complete failure to describe that invention in the original specification, including description and drawings

The answer to the first must be “yes,” and to the second, “no.” It must be apparent from the petition or supporting documents that the inventor intended to protect the invention that he or she seeks to protect by reissue. It must not be apparent that the inventor did not intend to protect that invention.

The following are some examples of situations where a reissue would be in order, assuming that the other requirements for reissue were satisfied.

a) Failure to claim the invention. The original patent did not accurately put into words what the patentee had intended to protect at the time of issue, because the patent agent failed to comprehend and claim the invention properly [19]. The fact that the original patent disclosed but did not claim the matter covered in the reissue may be a ground to reissue if it can be shown that there was intent to claim the subject matter [20].

b) Failure to claim broadly. The patentee wishes to claim a subcombination that was claimed only as part of a combination. A reissue may be permitted if the subcombination cannot perform in an environment different from that of the combination claimed. The patentee wishes to add claims supported by the original description that are intermediate in scope between the broadest claims cancelled during the prosecution of the original patent, in view of prior art cited by the examiner, and the broadest claim granted on the original patent. Extension of a range may be possible if the extension is fully supported by the specification of the original patent and if the claims of the original patent are unrealistically too limited. Extension must be justifiable, fully supported by the specification of the original patent and based on claims clearly unrealistically too limited [21].

c) Claiming too broadly. The patentee wishes to narrow the scope of the invention protected by amending the specification to delete matter the patentee had no right to claim. For instance, he or she may wish to narrow the scope of the claims because of the discovery of prior art after the patent was issued [22].

d) Adding narrower claims. The patentee wishes to add claims that are narrower in scope to those in the original patent while still retaining the broad claims of the original patent. This is permitted provided that the intent to protect the invention defined by the narrower claims in the original patent can be shown. This is treated as a case of "insufficient specification," since "specification" includes both description and claims.

e) Insufficient description. The patentee wishes to amend the description of an original patent in which the invention had been claimed but not adequately shown or described. New matter that is common knowledge may be added [23].

f) Claims of a different category. A reissue of the patent may be allowed in order to permit claims of different categories (such as product, process, apparatus and use of product) to be added, provided that the new claims are for the same invention claimed in the original patent and the subject matters defined by all the claims are so linked as to form a single general inventive concept in accordance with section 36 of the *Patent Rules*. A patent cannot be reissued with claims directed to different categories if the claims define an invention that differs from that disclosed in the original patent [24].

23.03.07 Unacceptable reasons for reissue (Item 3, Form 1)

Reissue is not permitted for the following purposes:

a) to add newly discovered matter, such as subject matter developed after issuance of the original patent [25] or subject matter which was unknown to the inventor and which he or she had no intention of describing or specifying or claiming in the original patent [26]

b) to reassert claims deliberately cancelled during the prosecution of the original patent in the face of an objection from the examiner, and with full knowledge of the relevant facts [27]

c) to insert claims broader in scope than claims deliberately cancelled during the prosecution of the original patent because of an objection made by the examiner, and with full knowledge of the relevant facts [28]

d) to reassert claims limited during the prosecution of the original patent to clear prior art, [29] to avoid a conflict [30] or to avoid claims broader than these

e) to insert claims which are of the same scope as the original claims and which provide the same protection as was provided by the original claims

f) to reassert subject matter that was withdrawn to avoid final action issued by an examiner; in having made the amendment, the application was deemed to have been carefully considered by the patentee [31]

g) to reassert claims that were cancelled because of a requirement for division made during the prosecution of the original patent, where the patentee had full knowledge of the relevant facts

h) to correct matter included in the petition, unless the reissue is made on other acceptable grounds irrespective of when the mistake in the petition was discovered, for example, to correct misjoinder of inventors [32] or previously regularly filed application(s) on which priority is requested

i) to take advantage of intervening legislation (such as amendments to the *Patent Act*) or court judgments

j) to change the claims because the patent is being circumvented by others (e.g. corrections based on the analysis of a competitor's product[33]), unless the patentee can show intent to protect in the original patent what is claimed in the reissue and a failure to do so by reason of error arising from inadvertence, accident or mistake

k) to combine the subject matters of two existing patents by surrendering each into a single reissue patent, thereby extending the prescribed period of protection for some of the matter [34]

l) to correct a patent that was judicially declared fundamentally invalid [35]

There may well be other reasons advanced for reissue that are not acceptable. An overall consideration is whether the patentee intended to protect subject matter but unintentionally failed to do so.

23.03.08 Intent to claim and error circumstance (Item 4, Form 1)

The patentee must satisfy the Commissioner that there was an intent to protect in the original patent that which is claimed in the reissue; otherwise reissue is not permitted. The onus is on the patentee to demonstrate his or her intent to protect to the Commissioner [36]. If this is not obvious from the original petition, the examiner requires evidence to that effect. Intent to claim may be established by evidence other than the specification [37]. The evidence of the inventors at the filing of the reissue petition cannot be used to establish intent [38]. The priority document, the prosecution and the specification of the original application may be used to determine the intent of the patentee [39]. Other related applications may be used to establish intent [40]. The patentee may not make amendments based on facts not set forth in the petition, nor add new facts to the petition for reissue.

The circumstances that transpired and how they resulted in an outcome that was different from the intent must be set out. Assuming that the other requirements for reissue are satisfied, acceptable circumstances for reissue are as follows:

a) Error of mistake or omission by the agent [41]

b) Error in understanding by the inventor or the agent leading to filing two applications for subject matters that the examiner later considered to be the same subject matter [42]

c) Error arising from the pressure of meeting deadlines [43]

d) Error due to a mix-up in the agent's office practice or behaviour [44]

e) Error due to misunderstanding of the effect of prosecution in a foreign country [45]

f) Even though pertinent prior art was brought to the attention of the agent before allowance of the original patent, the agent did not appreciate the significance of this prior art [46].

g) An error that came about by a deliberate act of the patentee but whose consequences were unintentional or not appreciated [47]. However, a deliberate act can be interpreted as intentional even where the legal implications are not appreciated [48].

h) Error arising from a miscommunication between the agent and the inventor [49]. The health condition of those involved may be a factor.

A language barrier between the inventor and the agent is acceptable as a contributing factor [50].

23.03.09 Discovery of the error (Item 5, Form 1)

The patentee must provide evidence to explain how the error that led to the filing of the reissue was discovered [51]. Merely stating that an error was committed is not sufficient. Rather, the manner in which the knowledge of the new facts was obtained must be fully described and must be consistent with the explanation in items 3 and 4 of Form 1. The error must have been discovered after the patent was issued or at least after the final fee was paid [52].

23.03.10 Examination of the reissue specification

Following the acceptance of the petition for reissue, the amended specification or "reissue specification" is examined. A review of the prosecution history of the original patent is necessary when a reissue application is examined. When new or amended claims are submitted with the reissue, the examiner may conduct further prior art searches. If new prior art is discovered that could have been applied against the original application, it may be applied against the claims of the reissue application. Prior art is considered in view of the original claim dates [53] (broader claims may have different claim dates).

- If the reissue specification is acceptable, the reissue is granted.
    - For reissues based on patents issued on applications filed before October 1, 1989, the reissue patent is published and given a new patent number using the main numbering series in use prior to October 1, 1989. The World Intellectual Property Organization (WIPO) Standard Code ST.16 is "E" for this type of document.
    - For reissues based on patents issued on applications filed after October 1, 1989, the reissue patent is published with the same patent number as the original patent. However, the WIPO Standard Code ST.16 "E" indicates that it is a reissue patent.
- When the amended specification does not comply with the *Patent Act* or the *Patent Rules*, the defects are identified in an office letter written under subsection 47(1) of the *Patent Act*; this letter will specify a three-month time limit for response.

- Following the patentee's response, the examiner may
  - allow the reissue application if the amendments in the response overcome the defects and/or the patentee's arguments are found to be persuasive
  - refer the case to the Patent Appeal Board (PAB) if the specification still does not comply with the *Patent Act* and the *Patent Rules*. Following the PAB advice, the Commissioner may refuse the reissue application.
- If the patentee does not respond within the specified three-month time limit, the Commissioner may refuse the reissue application. However, the patentee may argue that the reissue application is in compliance with the *Patent Act* and/or file a new petition along with a further reissue fee provided that the four-year time period has not expired.

23.03.11 Effect of the reissue and maintenance fees

When the reissue is granted, only the reissued patent is then considered, without regard to how any change came to be made in it as a result of the reissue [54]. The reissued patent is entitled to the unexpired term granted to the original patent. Subsection 47(2) of the *Patent Act* clearly describes the effect of a reissue regarding pending action:

> 47(2) The surrender referred to in subsection (1) takes effect only on the issue of the new patent, and the new patent and the amended description and specification have the same effect in law, on the trial of any action thereafter commenced for any cause subsequently accruing, as if the amended description and specification had been originally filed in their corrected form before the issue of the original patent, but, in so far as the claims of the original and reissued patents are identical, the surrender does not affect any action pending at the time of reissue or abate any cause of action then existing, and the reissued patent to the extent that its claims are identical with the original patent constitutes a continuation thereof and has effect continuously from the date of the original patent.

This generally applies in a suit for infringement or when the plaintiff in an action can obtain at least part of the remedy claimed [55].

No maintenance fees apply to a reissue application (subsection 100(2) of the *Patent Rules*). However, maintenance fees are payable on the reissued patent under the same conditions as the original patent (subsections 101(1) and (2) of the *Patent Rules*), i.e. in accordance with the maintenance fee due dates that apply to the original patent.

23.04 Clerical error corrections

Clerical errors in any instrument of record at the Patent Office may be corrected with the permission of the Commissioner under the provisions of section 8 of the *Patent Act*. No instrument of record at the Patent Office is exempt from correction under section 8 of the *Patent Act*.

Clerical errors originating from the patentee or applicant may be corrected in response to a clerical error request from the patentee or applicant. In this situation, payment of the prescribed fee is required (Schedule II, Part IV, Item 19 of the *Patent Rules*). Third parties willing to point out clerical errors originating from the patentee or applicant should contact the patentee, the applicant or the patent agent of record.

Clerical errors originating from the Patent Office can be discovered during quality control verification, examination or other procedures at the Patent Office, or from observations made by the applicant, the patentee or a third party. Since this type of correction is an internal procedure, no fee is levied. Similarly, no fee is levied for clerical errors originating from mistakes made by foreign patent offices, including international authorities.

The Commissioner will review the request under section 8 of the *Patent Act* and will decide whether or not the correction will be made, based on the nature of the error made. The Commissioner has the discretion and authority to correct clerical errors [56]. The Commissioner is not obliged to warrant the correction once it has been determined that a clerical error exists [57].

During the prosecution of an application, section 35 of the *Patent Rules* provides that the applicant can correct clerical errors in any document relating to an application, other than a specification, a drawing or a document effecting a transfer or a change of name (mainly assignments), that are due to the fact that something other than what was obviously intended was written, under the authority of the Commissioner [58].

23.04.01 Content of a clerical error request

There is no clerical error request form. The patentee or applicant requests the correction by

- describing the corrections being sought in a letter to the Commissioner, with reference to the patent or application number, and explaining the circumstances that led to the mistake justifying the correction. An explanation of the circumstances that led to the mistake is important in determining the origin and nature of the mistake.

- if applicable, paying the prescribed fee on requesting correction of a clerical error under section 8 of the Patent Act (Schedule II, Part IV, Item 19 of the *Patent Rules*)

- optionally, attaching the official copy bearing the Patent Office seal (also known as the “grant copy”) to the letter

Refunds of fees paid with a request for clerical error correction are not mandated by section 4 of the *Patent Rules*. The fee is levied for request processing by the Patent Office and does not depend on the acceptance or refusal of the corrections. When a clerical error request is made without the payment of the prescribed fee and the Patent Office determines that this fee is required based on the facts, the Patent Office notifies the patentee or applicant that a fee must be paid to proceed with the consideration under section 8 of the *Patent Act*.

23.04.02 Unacceptable clerical error request

If a request for the correction of a clerical error is refused, the requester will be informed in writing of the reason(s) for its refusal. Since the Commissioner has the discretion to issue a certificate of correction, the court cannot substitute its discretion therefor [59]. The applicant or patentee can seek correction by other means of correction, such as disclaimer or reissue, as applicable given the circumstances.

A first category of unacceptable clerical error requests refers to documents that are not instruments of record at the Patent Office:

1) Correction of international patent applications for which Canada is not designated or elected. Such applications are not instruments of record at the Patent Office as they do not represent validly filed applications in the Patent Office [60].

2) An act of omission referring to documents or parts of documents that are not instruments of record at the Patent Office

3) The replacement of entire parts of a patent or patent application, such as a complete description or a claim in its entirety, referring to material that is not an instrument of record

A second category of unacceptable clerical error requests refers to mistakes that are not clerical errors by nature:

4) Correction of a claim or claims due to lack of antecedence of some terms or expressions

5) Correction of translation mistakes (translation mistakes are not transcription mistakes)

A third category of unacceptable clerical error requests refers to corrections negatively affecting the rights of others:

6) Modification backdating the priority date [61], owing to a mistake by the applicant or patentee (Chapter 7 of MOPOP provides information about requesting priority)

7) Corrections having the effect of broadening the claims of a patent

8) Correction or revocation of a dedication or disclaimer of rights [62]

23.04.03 Effect of a clerical error correction

When the decision regarding a request to correct a clerical error is positive and affects a document registered at the Patent Office, the requester is informed by an office letter that the correction has been made and receives a certificate of correction listing all the changes applied to the instrument of record. For a granted patent, the certificate of correction is accompanied by a copy of the cover page, bearing the official stamp "see certificate - Correction - Article 8 voir certificat," and a copy of all the pages affected by the correction, bearing the official stamp "Section 8 Correction see certificate - Correction - Article 8 voir certificat." The Patent Office records are corrected accordingly.

The patent or patent application has to be read as it has always been read in its corrected form.

Endnotes for Chapter 23

1. Monsanto Co. v. Commissioner of Patents, [1975] 18 C.P.R. (2d) 170 at 178, reversed on other grounds, [1976] 28 C.P.R. (2d) 118.

2. Trubenizing Process Corp. v. John Forsyth, Ltd., [1942] 2 C.P.R. 89 at 106-107, reversed on other grounds, [1943] 3 C.P.R. 1

3. Standal's Patents Ltd. et al. v. Swecan International Ltd. et al., [1989] 28 C.P.R. (3d) 261 at 276

4. Monsanto Co. v. Commissioner of Patents, [1975] 18 C.P.R. (2d) 170 at 176-177, reversed on other grounds, [1976] 28 C.P.R. (2d) 118.

5. International Vehicular Parking Ltd. v. Mi-Co Meter (Canada) Ltd. and Guelph, [1948] 9 C.P.R. 97 at Sec. II, p. 112

6. ICN Pharmaceuticals, Inc. et al. v. Canada (Patented Medicine Prices Review Board), [1996]

   66 C.P.R. (3d) 45, affirmed 68 C.P.R. (3d) 417

7. Cooper & Beatty v. Alpha Graphics Ltd. et al., [1980] 49 C.P.R. (2d) 145 at 164

8. Canadian Celanese Ltd. v. B.V.D. Co. Ltd., [1939] 2 D.L.R. 289 at 294

9. Curl Master Mfg. Co. Ltd. v. Atlas Brush Ltd., [1967] 52 C.P.R. 51 at 72-73,
   reversing 48 C.P.R. 67 (also indexed as [1967] SCR 514 at 531-533)

10. Northern Electric Co. Ltd. et al. v. Photo Sound Corp. et al., [1936] S.C.R. 649 at 653

11. Curl Master Mfg. Co. Ltd. v. Atlas Brush Ltd., [1967] 52 C.P.R. 51 at 74,
    reversing 48 C.P.R. 67 (also indexed as [1967] SCR 514)

12. Mobil Oil Corp. et al. v. Hercules Canada Inc., [1994] 57 C.P.R. (3d) 488 at 501,
    reversed on other grounds, [1995] 63 C.P.R. (3d) 473
    Commissioner's Decision No. 326, Application No. 193998, [1976] at 13

13. Farbwerke Hoechst A.G. etc. v. Commissioner of Patents, [1966] 50 C.P.R. 220 at 255-256 & 259
    (also indexed as [1966] S.C.R. 604 at 615 & 617)
    Fuso Electric Works et al. v. Canadian General Electric Co. Ltd., [1940] SCR 371 at 381 & 385
    Bergeon v. De Kermor Electric Heating Co. Ltd., [1927] Ex. C.R. 181 at 191-192

14. Commissioner's Decision No. 1081, Application No. 342,635 (now Patent No. 1,271,356), [1986] at 7

15. Curl Master Mfg. Co. Ltd. v. Atlas Brush Ltd., [1967] 52 C.P.R. 51 at 52 & 70-71,
    reversing 48 C.P.R. 67 (also indexed as [1967] SCR 514)

16. Commissioner's Decision No. 56, Application No. 40,555 (now Patent No. 872,729), [1971] at 7

17. Apotex Inc. v. Hoffmann La-Roche Ltd., [1987] 15 C.P.R. (3d) 217 at 218 & 242,
    affirmed 24 C.P.R. (3d) 289
    Urea Casale S.A. v. Stamicarbon B.V., [2002] 17 C.P.R. (4th) 377 at 393, rev. 8 C.P.R. (4th) 206

18. Mobil Oil Corp. et al. v. Hercules Canada Inc., [1994] 57 C.P.R. (3d) 489 at 501,
    reversed on other grounds 63 C.P.R. (3d) 473
    In Re: Application for patent of Khallil (now Patent No. 1,147,604), [1983] 2 C.P.R. (3d) 343 at 351
    Re: Hewlett-Packard Co. Application, [1989] 31 C.P.R. (3d) 463 at 468
    Curl Master Mfg. Co. Ltd. v. Atlas Brush Ltd., [1967] 52 C.P.R. 51 at 52
    reversing [1965] 48 C.P.R. 67
    Apotex Inc. v. Hoffmann La-Roche Ltd., [1987] 15 C.P.R. (3d) 217 at 218,
    affirmed [1989] 24 C.P.R. (3d) 289

19. Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd., [1976] 17 CPR (2d) 97, (also indexed as 1 [1976] SCR 555 at 568), reversing 10 C.P.R. (2d) 126, reversing 7 C.P.R. (2d) 198

20. Leonard v. Commissioner of Patents, [1913] 14 ExCR 351 at 360
Commissioner's Decision No. 141, Application No. 60,764 (now Patent No. 940,336), [1973] at 9
Northern Electric Company Ltd. v. Photo Sound Corp., [1936] SCR 657 at 659, 660, and 665-666

21. Commissioner's Decision No. 667, Application 271,054 (now Patent No. 1,089,582), [1980] at 5

22. Flexi-Coil Ltd. v. F.P. Bourgault Industries Air Seeder Division Ltd., [1990] 31 C.P.R. (3d) 529 at 536, affirmed [1991] 35 C.P.R. (3d) 154
Rothmans, Benson & Hedges Inc. v. Imperial Tobacco Ltd./Ltée, [1991] 35 C.P.R. (3d) 417 at 430, affirmed on other grounds, [1993] 47 C.P.R. (3d) 188

23. Commissioner's Decision No. 56, Application No. 40,555 (now Patent No. 872,729), [1971] at 6-7

24. Fuso Electric Works et al. v. Canadian General Electric Co. Ltd., [1940] S.C.R. 371 at 385
Farbwerke Hoechst A.G. etc. v. Commissioner of Patents, [1966] 50 C.P.R. 220 at 241
(also indexed as [1966] Ex. C.R. 91 at 109-110, affirmed, [1966] S.C.R. 604)

25. Fuso Electric Works et al. v. Canadian General Electric Co. Ltd., [1940] S.C.R. 371 at 378
Creations 2000 Inc. et al. v. Canper Industrial Products Ltd. et al., [1988] 22 C.P.R. (3d) 389, affirmed, [1990] 34 C.P.R. (3d) 178 at 407
Mobil Oil Corp. et al. v. Hercules Canada Inc., [1994] 57 C.P.R. (3d) 488 at 498 and 499, reversed on other grounds, [1995] 63 C.P.R. (3d) 473
Re: Hewlett-Packard Co. Application, [1989] 31 C.P.R. (3d) 463 at 470

26. Commissioner's Decision No. 1034, Application No. 342200, [1984] at 7

27. Re: Wahpeton Canvas Co. Application Reissue, [1989] 31 C.P.R. (3d) 434 at 446
Notice by Assistant Commissioner, 10 C.P.R. (2d) 230 at 236
Re: Application No. 100,628 of Film Corp. of America, [1972] 11 C.P.R. (2d) 283 at 288
Commissioner's Decision No. 420, Application No. 225,214 (now Patent No. 1,027,403), [1977] at 1

28. Commissioner's Decision No. 906, Application No. 330,333, [1981]

29. Re: Halbrite Well Services Co. Patent Application No. 616,196, [1993] 3 C.P.R. (4th) 94 at 95
Commissioner's Decision No. 326, Application No. 193,998, [1976] at 9
Commissioner's Decision No. 134, Application No. 100,628 (now Patent No. 921,743), [1972] at 5

30. Re: Application of Wahpeton Canvas Co., [1989] 31 C.P.R. (3d) 434

31. Re: Halbrite Well Services Co. Patent Application No. 616,196, [1993] 3 C.P.R. (4th) 94 at 95

32. Re: Application of Westinghouse Electric Corp., [1980] (now Patent No. 1,101,791), 63 C.P.R. (2d) 153 at 156

33. Re: Application of Hewlett-Packard Co., [1989] 31 C.P.R. (3d) 463 at 470

34. Re: Application for reissue of Wahpeton Canvas Co., [1989] 31 C.P.R. (3d) 434 at 451

35. Creations 2000 Inc. et al. v. Canper Industrial Products Ltd. et al., 22 C.P.R. (3d) 389 at 406, affirmed 34 C.P.R. (3d) 178

36. Mobil Oil Corp. et al. v. Hercules Canada Inc., [1994] 57 C.P.R. (3d) 489 at 498, reversed on other grounds, *[1995] 63 C.P.R. (3d) 473 at 499*

37. Northern Electric Company Limited v. Photo Sound Corp., [1936] S.C.R. at 659
    Fuso Electric Works et al. v. Canadian General Electric Co. Ltd., [1940] S.C.R. 371 at 380

38. Mobil Oil Corp. et al. v. Hercules Canada Inc., [1994] 57 C.P.R. (3d) 489 at 499,
    reversed on other grounds, [1995] 63 C.P.R. (3d) 473
    Commissioner's Decision No. 1095, Application No. 400,496 (now Patent No. 1,220,002), [1986] at 6

39. Northern Electric Company Ltd. v. Photo Sound Corporation, [1936] S.C.R. at 649 and 635
    Mobil Oil Corp. et al. v. Hercules Canada Inc., [1994] 57 C.P.R. (3d) 489 at 498 and 499,
    reversed on other grounds, [1995] 63 C.P.R. (3d) 473
    Commissioner's Decision No. 1173, Application No. 615,585 (now Patent No. 1,258,156), [1992]
    Commissioner's Decision No. 326, Application No. 193,998, [1976] at 10
    Commissioner's Decision No. 77, Application No. 9,562 (now Patent No. 930,656), [1971] at 3
    Commissioner's Decision No. 134, Application No. 100,628 (now Patent No. 921,743), [1972] at 4
    Commissioner's Decision No. 1066, Application No. 379,817 (now Patent No. 1,217,519), [1986] at 9

40. Commissioner's Decision No. 326, Application No. 193,998, [1976] at 11 and 12

41. Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd., [1976] 17 CPR (2d) 97 at 108, (also indexed as 1 [1976] SCR 555 at 568), reversing 10 C.P.R. (2d) 126, reversing 7 C.P.R. (2d) 198

42. Re: Application of Westinghouse Electric Corp., [1980] (now Patent No. 1,101,791), 63 C.P.R. (2d) 153 at 156

43. Cabot Corp. v. 318602 Ontario Ltd., [1988] 20 C.P.R. (3d) 132 at 134

44. Mobil Oil Corp. et al. v. Hercules Canada Inc., [1994] 57 C.P.R. (3d) 489 at 498,
    reversed on other grounds, [1995] 63 C.P.R. (3d) 473
    Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd., [1976] 17 CPR (2d) 97 at 108, (also indexed as 1 [1976] SCR 555 at 568), reversing 10 C.P.R. (2d) 126, reversing 7 C.P.R. (2d) 198

45. Commissioner's Decision No. 56, Application No. 40,555 (now Patent No. 872,729), [1971] at 6-7

46. Commissioner's Decision No. 40, Application No. 1,820 (now Patent No. 866,300), [1970] at 6

47. Mobil Oil Corp. et al. v. Hercules Canada Inc., [1994] 57 C.P.R. (3d) 489 at 500,
    reversed on other grounds, [1995] 63 C.P.R. (3d) 473
    Hydril Patent Application No. 616,666, [1997] 85 C.P.R. (3d) 503 at 509

48. Commissioner's Decision No. 906, Application No. 330,333, [1981] at 10

49. Curl Master Mfg. Co. Ltd. v. Atlas Brush Ltd., [1967] 52 C.P.R. 51 at 69
    reversing [1965] 48 C.P.R. 67

50. Commissioner's Decision 1173, Application No. 615,585 (now Patent No. 1,320,323), [1992] at 8-9
Commissioner's Decision 123, Application No. 96,160 (now Patent No. 921,510), [1972] at 2

51. Paul Moore Co. Ltd. v. Commissioner of Patents, [1979] 46 C.P.R. (2d) 5 at 10
Commissioner's Decision No. 104, Application No. 104,168 (now Patent No. 914,704), [1972] at 2
Commissioner's Decision No. 26, Application No. 975,082 (now Patent No. 862,687), [1970]

52. Commissioner's Decision No. 1093, Application No. 371,218 (now Patent No. 1,230,339), [1986] at 6
Commissioner's Decision No. 1173, Application No. 615,585 (now Patent No. 1,258,156), [1992]

53. Energy Absorption Systems Inc. v. 2859-7888 Québec Inc. et al., [1993] 53 C.P.R. (3d) 397 at 399

54. O'Cedar of Canada Ltd. v. Mallory Hardware Products Ltd., [1955], 24 C.P.R. 103 at 132

55. Continental Can Co. of Canada Ltd. v. Wainberg, [1969] 61 C.P.R. 159 at 160

56. Bristol-Myers Squibb Co. v. Canada (Commissioner of Patents), [1998] 82 C.P.R. (3d) 192 at 197, affirming [1997] 77 C.P.R. (3d) 300. "The current section 8 no longer requires a certificate but maintains the requirement that the correction be made under the authority of the Commissioner, ..."

57. Bayer Aktiengesellschaft v. Commissioner of Patents, [1980] 53 C.P.R. (2d) 70 at 74. "There is nothing in the circumstances contemplated by s. 8 that would lead me to conclude that the respondent is obliged to issue a certificate of correction once he determines that what is sought to be corrected is a clerical error. It is in his discretion to do so. The Court cannot substitute its discretion for his."
The Upjohn Co. v. Commissioner of Patents et al., [1983] 74 C.P.R. (2d) 228 at 232-233

58. Bristol-Myers Squibb Co. v. Canada (Commissioner of Patents), [1998] 82 C.P.R. (3d) 192 at 197, affirming [1997] 77 C.P.R. (3d) 300. "... and the current rule 35 provides that the correction is to be made by the applicant, ostensibly under the authority of the Commissioner."

59. Bayer Aktiengesellschaft v. Commissioner of Patents, [1980] 53 C.P.R. (2d) 70 at 74

60. Celltech Ltd. v. Canada (Commissioner of Patents), [1993] 46 C.P.R. (3d) 424 at 435 & 441, affirmed [1994] 55 C.P.R. (3d) 59

61. Bristol-Myers Squibb Co. v. Canada (Commissioner of Patents), [1998] 82 C.P.R. (3d) 192 at 199-200, affirming [1997] 77 C.P.R. (3d) 300

62. Parke Davis, [2001] 14 C.P.R. (4th) 335 para 102 to 107, reversed on other grounds 2002 FCA 454

Chapter 24
Maintenance fees

24.01 Scope of this chapter

This chapter outlines the Patent Office policy respecting the fees to be paid to maintain patent applications and patents, and the procedures and time limits relating to the payment of maintenance fees.

24.02 Maintenance of patent applications

An applicant who files a patent application in Canada after October 1, 1989 must pay maintenance fees for prescribed periods in order to keep the application in effect (subsection 27.1(1) of the *Patent Act*).

Divisional applications carry their own maintenance fees, separate from the parent application. Since a properly filed divisional application will bear the filing date of the parent application, a divisional application is, at the time of filing, subject to fees to maintain the application in effect. Such fees will be calculated from the filing date of the parent application and are payable upon filing of the divisional application (subsections 99(3), and 154(3) of the *Patent Rules*). For example, if a divisional application is to be filed 40 months after the parent application, maintenance fees for the 2nd and 3rd years have to be paid upon of the divisional application.

Applications filed under the provisions of the Patent Cooperation Treaty and entering the national phase in Canada must pay maintenance fees in accordance with part VI of Schedule 2 of the *Patent Rules*. It should be noted that the international filing date is the date on which the maintenance fee Schedule is based.

Maintenance fees do not have to be paid on an application for reissue of a patent (sections 101, 156 and 182 of the *Patent Rules*). The applicant must continue to pay maintenance fees on the patent being reissued.

24.02.01 Due dates for application maintenance fees

In order to maintain a patent application in effect, an applicant must pay maintenance fees for each one-year period from the second anniversary of the filing date of the application. Whether or not the application issues to patent the maintenance fees will continue to be due on the same schedule until the last payment is made before the nineteenth anniversary, which covers the period from the nineteenth anniversary to the twentieth anniversary, which represents the full term of the patent. The time limit for paying each maintenance fee is given in Item 30, Part VI of Schedule II of the *Patent Rules*. Part VI of Schedule II of the *Patent Rules* is reproduced in section 25.06 of the present manual.

The maintenance fee for an application must be paid before the first day of the one-year period the fee covers. For example, the maintenance fee covering the one-year period ending on the fifth anniversary of the filing of the application must be paid on or before the fourth anniversary of the filing date.

Any or all of the maintenance fees for a particular application or a patent may be paid in advance.

Time limits for payment of maintenance fees cannot be extended.

24.02.02 Responsibility for payment of maintenance fees for applications

Only the applicant or the authorized correspondent shall pay maintenance fees. The amounts are set forth in Item 30, Part VI of Schedule II of the *Patent Rules*. The authorized correspondent is responsible for ensuring the timely payment of maintenance fees. The Patent Office will send a reminder to the authorized correspondent that the payment of the first maintenance fee is approaching. This will be a one time notice mailed approximately three months in advance of the second anniversary of the application's filing date.

24.02.03 Non-payment of application maintenance fees

Non-payment of maintenance fees will result in abandonment of the application under subsection 73(1) of the *Patent Act*. The authorized correspondent will normally be advised in a notice of abandonment that applicant's application is abandoned for failure to pay the maintenance fee by the due date. For details on the reinstatement procedure for abandoned applications (see section 20.08 of the present manual).

24.03 Maintenance of patents

Maintenance fees for patents issued on the basis of applications filed after October 1, 1989 are payable for each one year period between the second and twentieth anniversaries of the date of filing of the application in Canada. Maintenance fees for patents issued on or after October 1, 1989 on the basis of an application filed before October 1, 1989 are payable for each one year period between the second and the seventeenth anniversaries of the date on which the patent was issued.

No maintenance fee for a patent is due for any period where a maintenance fee was paid to maintain the patent application in effect.

Maintenance fees for reissue patents are due at the same times and for the same periods as the original patent for the unexpired term of the original patent. No fee to maintain the rights accorded to a reissue patent is payable for any period where a maintenance fee was paid to maintain the original patent or to maintain the application for the original patent (section 101 of the *Patent Rules*).

24.03.01 Due dates for patent maintenance fees

Maintenance fees are due before the first day of each of the one-year periods they cover. For example, payment is due on or before the eleventh anniversary for the one year period ending on the twelfth anniversary. The time limits for maintenance fees for patents are given in Items 31 and 32 of Part VI of Schedule II of the *Patent Rules*, included as Section 25.06 of this manual.

Late payment of the maintenance fees for patents are also accepted by the office if the payment is made within the one year period the fee covers and the prescribed late payment fee is also paid. For example, the maintenance fee for the one year period ending on the seventeenth anniversary of the filing date can be made, with the additional fee for late payment, on or before the seventeenth anniversary date. Any or all of the maintenance fees for a particular application or a patent resulting from that application may be paid in advance.

The time limits for payment of maintenance fees for patents cannot be extended.

24.03.02 Responsibility for payment of maintenance fees

The patentee is responsible for ensuring the timely payment of maintenance fees. The Patent Office will not send a reminder to the patentee that a date for the payment of a maintenance fee is approaching.

24.03.03 Non-payment of patent maintenance fee

A patent is deemed to have lapsed at the expiration of the time specified in Part VI of Schedule II of the *Patent Rules* (subsection 46(2) of the *Patent Act*) for payment of maintenance fees. A lapsed patent cannot be revived. See also section 20.09 of MOPOP on Lapsed Patent. If the maintenance fee on a patent is not paid on or before the anniversary date the Patent Office will normally inform the patentee that a late payment fee must be paid within one year following the anniversary or the patent will lapse.

24.04 Schedule of maintenance fees

The tariff of the maintenance fees are listed in Part VI of Schedule II (Section 3) of the *Patent Rules*, and in section 25.06 of the present manual.

24.05 Maintenance fee information on the Canadian Patent Database (CPD)

Maintenance fee information is accessible on the administrative status page ("View administrative status") of the Canadian Patent Database at:

(http://patents1.ic.gc.ca/intro-e.html).

Maintenance fee information includes the date and amount of the last payment received, the date and amount of the next payment if the applicant or grantee is a small entity type and the date and amount of the next payment if the applicant or grantee is a large entity type.

Expired status is defined as: “In cases where all maintenance fees required by section 46 of the *Patent Act* were paid, the day at the end of which the patent term expired, pursuant to section 44 or 45 of the *Patent Act*.

Chapter 25
Tariff of Fees (effective July 26, 2004)

25.00 Introduction

This chapter sets forth the various fees to be collected by the Patent Office for services rendered to its clients. The general provision for the charging of fees for service is section 12(1)(*e*), (*f*) and (*g*) of the *Patent Act* and section 3 of the *Patent Rules*. The fees are specified in Schedule II (Section 3) of the *Patent Rules*.

The fees are listed in the following Sections.

25.00.01 Transitional provisions (effective January 1st, 2004)

Maintenance fees paid before January 1, 2004, are paid according to the tariff of fees listed as items 30 to 32 of Schedule II of the *Patent Rules* as they read immediately before January 1, 2004. Maintenance fees paid after January 1, 2004, are paid according to the tariff of fees listed as items 30 to 32 of Schedule II of the *Patent Rules* as in force on January 1, 2004 (section 24 of the Transitional Provisions of the *Rules Amending the Patent Rules* SOR/2003-208).

For patent application deemed to be abandoned for failure to pay a prescribed fee before January 1, 2004, the amount of the fee that must be paid for the purposes of paragraph 73(3)(*b*) of the *Patent Act* to reinstate the application is the amount set out in Schedule II of the *Patent Rules* as they read on the date of abandonment (section 25 of the Transitional Provisions of the *Rules Amending the Patent Rules* SOR/2003-208).

For patent application filed on or after October 1, 1989, when a notice of allowance, pursuant to subsection 30(1) or 30(5) of the *Patent Rules*, is sent before January 1, 2004, the amount of the final fee that must be paid is set out in item 6(*a*) of Schedule II of the *Patent Rules* as they read immediately before January 1, 2004 (section 26 of the Transitional Provisions of the *Rules Amending the Patent Rules* SOR/2003-208).

25.01 Part I of Schedule II (Section 3) of the *Patent Rules* - Applications

Item	Service for which fees are charged or will be charged	Fee
Item 1	On filing an application under subsection27(2) of the *Patent Act*	$200 (Small entity) $400 (Large entity)
Item 2	On completing an application under subsection 94(1) of the *Patent Rules* or on avoiding a deemed abandonment under subsection 148(1) of the *Patent Rules*	$200
Item 3	On requesting examination of an application under subsection 35(1) of the *Patent Act*	
	(*a*) if the application has been the subject of an international search by the Commissioner	$100 (Small entity) $200 (Large entity)
	(*b*) except if paragraph (*a*) applies	$400 (Small entity) $800 (Large entity)
Item 4	On requesting the advance of an application for examination under section 28 of the *Patent Rules*	$500
Item 5	On filing an amendment under subsection 32(1) of the *Patent Rules*, after a notice is sent pursuant to subsection 30(1) or (5) of the *Patent Rules*	$400
Item 5	On filing an amendment under subsection 32(1) of the *Patent Rules*, after a notice is sent pursuant to subsection 30(1) or (5) of the *Patent Rules*	$400
Item 6	Final fee under subsection 30(1) or (5) of the *Patent Rules*	
	(*a*) For applications filed on or after October 1, 1989:	
	(i) basic fee	$150 (Small entity) $300 (Large entity)
	(ii) plus, for each page of specification and drawings in excess of 100 pages	$6
	(*b*) For applications filed before October 1, 1989:	
	(i) basic fee	$350 (Small entity) $700 (Large entity)
	(ii) plus, for each page of specification and drawings in excess of 100 pages	$4
Item 7	On requesting reinstatement of an abandoned application	$200
Item 8	On applying for restoration of a forfeited application under subsection 73(2) of the *Patent Act* as it read immediately before October 1, 1989	$200

25.02 Part II of Schedule II (Section 3) of the *Patent Rules* - International Applications

Item	Service for which fees are charged or will be charged	Fee
Item 9	Transmittal fee under Rule 14 of the Regulations under the PCT	$300
Item 9.1	Search fee under Rule 16 of the Regulations under the PCT	$1,600
Item 9.2	Additional fee under Rule 40 of the Regulations under the PCT	$1,600
Item 9.3	Preliminary examination fee under Rule 58 of the Regulations under the PCT	$800
Item 9.4	Additional fee under Rule 68 of the Regulations under the PCT	$800
Item 10	Basic national fee under paragraph 58(1)(*c*) of the *Patent Rules*	$200 (Small entity) $400 (Large entity)
Item 11	Additional fee for late payment under subsection 58(3) of the *Patent Rules*	$200

25.03 Part III of Schedule II (Section 3) of the *Patent Rules* - Patents

Item	Service for which fees are charged or will be charged	Fee
Item 12	On filing an application to reissue a patent under section 47 of the *Patent Act*	$1,600
Item 13	On making a disclaimer to a patent under s.48 of the *Patent Act*, or of the *Patent Act* as it read immediately before October 1, 1989	$100
Item 14	On requesting re-examination of a claim or claims in a patent under subsection 48.1(1) of the *Patent Act*	$1,000 (Small entity) $2,000 (Large entity)
Item 15	On requesting registration of a judgment under section 62 of the *Patent Act* , or of the *Patent Act* as it read immediately before October 1, 1989	$50
Item 16	On presenting an application to the Commissioner under subsection 65(1) of the *Patent Act*:	
	(*a*) for the first patent to which the application relates	$2,500
	(*b*) for each additional patent to which the application relates	$250
Item 17	On requesting an advertisement of an application under subsection 65(1) of the *Patent Act* in the *Patent Office Record* in accordance with subsection 68(2) of the *Patent Act*	$200
Item 18	On requesting publication in the *Patent Office Record* of a notice listing the patent numbers of patents available for license or sale, other than at the time of issuance of the patent, for each patent number listed	$20

25.04 Part IV of Schedule II (Section 3) of the *Patent Rules* - General

Item	Service for which fees are charged or will be charged	Fee
Item 19	On requesting correction of a clerical error under section 8 of the *Patent Act*, or of the *Patent Act* as it read immediately before October 1, 1989	$200
Item 20	On giving notice to the Commissioner of a new representative or a change in address, or on supplying a new and correct address under subsection 29(3) of the *Patent Act*, or of the *Patent Act* as it read immediately after October 1, 1989	N/A (Repeal)
Item 21	On requesting registration of a document under section 49 or 50 of the *Patent Act*, or of the *Patent Act* as it read immediately before October 1, 1989, or under section 37, 38, 39 or 42 of the *Patent Rules*, for each patent or application to which the document relates	$100
Item 22	On applying for an extension of time under subsection 26 or 27 of the *Patent Rules*	$200
Item 22.1	Late payment fee under subsection 3.1(1) of the *Patent Rules*	Greater of 50$ and 50% of the amount of the fee that has not been paid

25.05 Part V of Schedule II (Section 3) of the *Patent Rules* - Information and copies

Item	Service for which fees are charged or will be charged	Fee
Item 23	On requesting information respecting a pending application under section 11 of the *Patent Act*	$100
Item 24	On requesting information on whether a patent has issued, on the basis of an application filed in Canada and identified by a serial number	$20
Item 25	On requesting a copy of a document, for each page	
	(*a*) if the person requesting makes the copy using Patent Office equipment	$0.50
	(*b*) if the Patent Office makes a copy	$1.00
Item 25.1	On requesting a copy in electronic form of a document,	
	(*a*) for each request	$10
	(*b*) plus, for each patent or application to which the request relates	$10
	(*c*) plus, if the copy is requested on a physical medium, for each physical medium requested in addition to the first	$10
	(*d*) plus, for each additional 10 megabytes or part of them exceeding 7 megabytes	$10
Item 26	On requesting a certified copy of a document:	
	(*a*) for each certification	$35
	(*b*) plus, for each page	$1
Item 26.1	On requesting a certified copy in electronic form of a document	
	(*a*) for each certification	$35
	(*b*) plus, for each patent or application to which the request relates	$10
	(*c*) plus, for each additional 10 megabytes or part of them exceeding 7 megabytes	$10
Item 27	On requesting that the Patent Office provide information concerning the status of a patent application or patent, for each application or patent	$15
	On requesting a copy of a Canadian patent identified by any of serial numbers 1 to 445,930	(Repeal, included in item 25)
Item 28	On requesting a copy of an audio magnetic tape	$50
Item 29	On requesting a transcript of an audio magnetic tape, for each page in the transcript	$50

25.06 Part VI of Schedule II (Section 3) of the *Patent Rules* - Maintenance Fees

Item	Service for which fees are charged or will be charged	Fee
Item 30	For maintaining an application filed on or after October 1, 1989 in effect, under ss.99 and 154 of the *Patent Rules*	Large entity Yr 2-4 - $100 Yr 5-9 - $200 Yr 10-14 - $250 Yr 15-19 - $450 (Small entity 50% of large entity)
Item 31	For maintaining the rights accorded by a patent issued on the basis of an application filed on or after October 1, 1989, under sections 100, 101, 155 and 156 of the *Patent Rules*	Large entity Yr 2-4 - $100 Yr 5-9 - $200 Yr 10-14 - $250 Yr 15-19 - $450 (Small entity 50% of large entity) Large entity including an additional fee for late payment Yr 2-4 - $300 Yr 5-9 - $400 Yr 10-14 - $450 Yr 15-19 - $650 (Small entity 50% of the applicable maintenance fee for a large entity plus $200 for the late payment)
Item 32	For maintaining the rights accorded by a patent issued on or after October 1, 1989 on the basis of an application filed before that date, under subsections 182(1) and (3) of the *Patent Rules*	Large entity Yr 2-4 - $100 Yr 5-9 - $200 Yr 10-14 - $250 Yr 15-19 - $450 (Small entity 50% of large entity) Large entity including an additional fee for late payment Yr 2-4 - $300 Yr 5-9 - $400 Yr 10-14 - $450 Yr 15-19 - $650 (Small entity 50% of the applicable maintenance fee for a large entity plus $200 for the late payment)

25.07 Part VII of Schedule II (Section 3) of the *Patent Rules* - Patent Agents

Item	Service for which fees are charged or will be charged	Fee
Item 33	On applying for entry on the register of patent agents under section15 of the *Patent Rules*	$350
Item 34	On notifying the Commissioner pursuant to subsection14(2) of the *Patent Rules*, of a proposal to sit for the whole or any part of the qualifying examination, per paper	$200 per paper for a maximum of 4 papers
Item 35	For maintaining the name of a patent agent on the register of patent agents pursuant to paragraph 16(1)(*a*) of the *Patent Rules*	$350
Item 36	On applying to the Commissioner for reinstatement on the register of patent agents under section 17 of the *Patent Rules*	$200